IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON
TRANSCRIPT OF PROCEEDINGS

JACQUELYN TYREE, et al., **CIVIL ACTION NO.**

Plaintiffs, **2:12-cv-08633**

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

TRIAL DAY THREE

NOVEMBER 04, 2014

BEFORE THE HONORABLE IRENE C. BERGER,

UNITED STATES DISTRICT JUDGE

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I N D E X

PROCEEDINGS had before The Honorable Irene C. Berger, Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on November 04, 2014, at 8:50 a.m., as follows:

THE COURT: Good morning, everyone.

It's my understanding you have a preliminary matter.

MR. ADAMS: We do, Your Honor, and I can be brief about it.

Mr. Monsour was kind enough to give me his slides that he's going to use with this next witness. And a couple of the slides deal with opinions relating to the Directions for Use which, you know, has been described as kind of a manual for the Obtryx.

And, so, there's two slides. One is actually going through the manual or the DFU, and the second slide is called "Complications Not in the DFU." So, I anticipate this would be a description of why the Directions for Use is not appropriate because it doesn't have certain complications noted in it.

But I object to that and I informed Mr. Monsour of that. There's no discussion at all contained within this expert's Rule 26 report about any criticisms of the DFU and we weren't alerted to that. We didn't -- that wasn't an issue that was discussed with him. So, I think it's outside the scope.

I wanted to alert the Court and counsel to that because I didn't want to disrupt the exam later. I thought it would be best if we do it now.

THE COURT: Mr. Monsour.

MR. MONSOUR: Yes, Your Honor. I did not try to hide the ball at all from Mr. Adams. I came in this morning and, as he requested, I think we sent him the Power slides even before they asked, not just five minutes before he came, trying to give full disclosure.

I went through and I tracked Judge Goodwin's order. And when Judge Goodwin wrote his order with regard to Dr. Rosenzweig, he specifically said, "I'm going to let Dr. Rosenzweig talk about general causation." And in the context of general causation he even went further to say he can talk about shrinkage, degradation, and those types of things.

Well, the, the, the portions of the DFU -- we're not talking about the entirety of the DFU. But several portions of the DFU that we are going to talk about relate to the conditions of shrinkage and degradation.

And, so, it talks about the chronic problems, the inability to remove the mesh. Those all have to do with the, the in-growth, the shrinkage and degradation which make it almost impossible.

So, it's going to be a situation where we're talking about how the DFU relates to shrinkage and degradation which

has already been allowed. And there were no limitations put on Judge Goodwin's order about how far he can go on shrinkage and degradation. So, I think this falls right in line with Judge Goodwin's ruling, Your Honor.

MR. ADAMS: And, Your Honor, obviously Judge Goodwin, like us, was basing his *Daubert* opinion, which is on Page 84 and 85, basing it upon the confines of Rule 26 which says that your opinions have to be disclosed in the report.

There is nothing in the report concerning the DFU. So, Judge Goodwin nor us addressed opinions regarding the DFU, and that's why this expert shouldn't be allowed to testify about it.

Now, I mean, that's a pretty simple argument. Mr. Monsour, you know, has not pointed out anywhere in the report and there's nothing in the report that contains that language or those opinions.

THE COURT: All right. Anything further, counsel?

MR. MONSOUR: The only thing I would say is, Your Honor, it's hard to talk about medical problems and talk about every potential contingency that you might talk about. Instead, we give general topics that we might talk about, shrinkage and contraction.

Mr. Adams is a good lawyer. He knows that if we're talking about shrinkage contraction that the issue of the DFU might come up because it does come up because they don't warn

about it in the Directions for Use. They don't talk about how because the products contract that they are difficult to remove.

And, so, it falls under -- when you give somebody like Mr. Adams notice of something like that, he knows what we're going to talk about. It's not, it's not an undue prejudice or anything like that. It's, it's well within what we have talked about in this litigation the entire time. We talk about the Directions for Use.

At some point in time, I don't think we should even have to say that we're going to talk about the Directions for Use because we talk about it everything, in everything we do. It's almost an assumption.

THE COURT: All right, counsel, I would like to be able to give you a ruling here this morning before we get started so that you do not have to interrupt. But I myself want to hear the context of the testimony so that I can better understand and give you a more informed ruling on it.

I will listen carefully and make every effort to do that. But listening to your arguments isn't helping me. I would like to see the context.

Certainly, generally if it's an opinion that hasn't been disclosed, that's the reason for the rule, generally those are excluded. But if there is an opinion that may necessarily take into consideration discussions of other

matters that the Judge has not excluded, it would not necessarily be excluded because some sub category of opinion hasn't been disclosed.

So, I need to hear it, see the context in which it's going to be offered, and then I'll give you gentlemen a ruling.

MR. MONSOUR: Thank you.

MR. ADAMS: Your Honor, would it be helpful for you to have his expert report?

THE COURT: I do have it. I'm sorry. Yes, give me the expert report.

MS. WEILER: Your Honor --

THE COURT: Yes, ma'am.

MS. WEILER: -- we're also wondering if we could move a joint exhibit, the medical records in at this time.

THE COURT: All right.

MS. WEILER: As joint, joint exhibit we'd like to move the medical records of Ms. Tyree, and then separately as a joint exhibit the medical records of Ms. Blankenship. We would also like to do that for Ms. Wilson a little bit later, but we wanted to make sure we have the redactions right on that one.

THE COURT: All right. You want to give me, Ms. Weiler, the number of the exhibits and then I'll inquire if there's anything additional that the plaintiffs want to add

with respect to that motion.

MR. MONSOUR: Your Honor, would you like a copy of the *Daubert* opinion with regard to Dr. Rosenzweig?

THE COURT: I have that.

MR. MONSOUR: Okay, all right.

THE COURT: I'm sorry, Ms. Weiler. Mr. Monsour was being very discourteous to you. Go ahead.

MS. WEILER: Thank you, Your Honor.

Do you want all the exhibit numbers for each one of the exhibits within that joint collection?

THE COURT: So, it's not a collective exhibit then?

MS. WEILER: We've done one exhibit number per, per provider per plaintiff. So, I'm happy to read all of those, whatever is most convenient for the Court.

THE COURT: I want the record to be clear as to what's being offered, so let's go through it, please.

MS. WEILER: Okay. So, we'd like to offer Joint Exhibit Number 61, the medical records of Ryan FitzWater for Ms. Tyree; Joint Exhibit Number 62, the medical records of Ms. Tyree from Dr. John Hannah; Exhibit Number 63, medical records of Ms. Tyree from Dr. Joshua Lohri; Exhibit Number 64, Ms. Tyree's medical records from Dr. Bernard Luby; Exhibit Number 65, medical records of Ms. Tyree from Dr. David Patton; Exhibit Number 66, medical records of Ms. Tyree from Dr. Matthew Upton; Exhibit -- hold on one second. Sorry.

Actually, Number 66 is the medical record of Ms. Tyree as to Thomas Memorial Hospital; Exhibit Number 67 is the medical record of Ms. Tyree as to Dr. Matthew Upton; Exhibit Number 68 are the pharmacy records of Ms. Tyree from CVS Pharmacy. That's all for plaintiff Tyree, Your Honor.

THE COURT: With respect to plaintiff Tyree is there anything further that the plaintiffs want to put on the record with respect to the motion to admit those joint exhibits into evidence?

MS. WAGSTAFF: Yes, Your Honor. This is Aimee Wagstaff. We were handed this morning some medical bills relating to Ms. Tyree. I don't know if you're intending to use these with her or not, but we would object to admitting any medical bills with relation to her treatment. We're not seeking medical expenses or the recovery of them.

MR. BONASSO: They're in the, they're in the -- may I respond, Your Honor?

THE COURT: Sure.

MR. BONASSO: Ms. Weiler was speaking. Those bills were in the records. They're a part of the record. I believe it goes to the treatment that she had and the amount of treatment she had. They total about $16,000 for the two surgeries that she had. And I don't really intend to post the records in front of the jury, but I do intend to ask Ms. Blankenship if she recalls that and may demonstrate a summary

slide. It's relevant to the extent of plaintiff's claimed damages.

THE COURT: It's my understanding that they are not claiming those medical damages. Is that correct?

MS. WAGSTAFF: That's correct, Your Honor.

THE COURT: Then in an effort to ensure that there is no confusion on the jury's part and looking at these exhibits that are admitted, I'm going to exclude that portion from the records.

And I preserve, Mr. Bonasso, an objection and exception for the defendants.

Anything else with respect to the motion of joint exhibits related to plaintiff Tyree?

MR. LOVE: We have nothing further, Your Honor.

THE COURT: Ms. Weiler, those exhibits will be admitted into evidence.

MS. WEILER: Thank you, Your Honor. May I do the same for Ms. Blankenship as well?

THE COURT: Yes, ma'am.

MS. WEILER: I'd like to move for Joint Exhibit Number 1, which are the Access Health records pertinent to Ms. Blankenship; Exhibit Number 2, the CAMC Health Systems, Inc., records pertinent to Ms. Blankenship; Exhibit Number 3, the CAMC lab records pertinent to Ms. Blankenship; Exhibit Number 4, the Camden on Gauley Medical Center records pertinent as to

Ms. Blankenship; Exhibit Number 5, the medical records of Ms. Blankenship from Dr. Susan Capelle; Exhibit Number 6, the CVS Pharmacy records pertinent to Ms. Blankenship; Exhibit Number 7, the medical records from Carlotta Ray Evans, M.D., pertinent to Ms. Blankenship; Exhibit Number 8, Ms. Blankenship's records from Greenbrier Valley Medical Center; Exhibit Number 9, medical records regarding Ms. Blankenship from Monongalia General Hospital; Exhibit Number 10, the records regarding -- I'll drop that one -- Exhibit Number 11, medical records of Ms. Blankenship from Dr. Marnie Moose, actually FMP Marnie Moose; the pharmacy records regarding Ms. Blankenship from Mountain Lake Pharmacy; --

MS. WAGSTAFF: Your Honor, maybe to speed this up we could just say that we have no objection to any of those records coming in with the exception of the medical bills that we discussed.

THE COURT: She has moved on to a different plaintiff. I've ruled on the admissibility of those related to Ms. Tyree which is the plaintiff that I thought the issue was with respect to the medical bills.

MS. WAGSTAFF: Your Honor, Ms. Blankenship is not making a claim for medical bills either and --

MS. WEILER: Your Honor, I'm not asking -- I'm not asking to have admitted the medical bills. I'm just going through medical records for exhibit purposes.

THE COURT: All right. Go ahead, please.

MS. WEILER: Pharmacy records of Ms. Blankenship as Exhibit 13; the medical records of Ms. Blankenship from Dr. Jodie Posey as Exhibit 14; medical records of Ms. Blankenship from Dr. David Rainey as Exhibit 16; medical records of Ms. Blankenship from Robert Stanley D.O. as Exhibit 17; medical records regarding Ms. Blankenship for Summersville Regional Medical Center as Exhibit 18; and Exhibit 19 are the medical records regarding Ms. Blankenship from Summersville Rural Health Clinic; and, finally, medical records regarding Ms. Blankenship from Dr. Robert Wheeler as Exhibit 20, Your Honor.

THE COURT: All right. There was no 12. Is that correct?

MS. WEILER: That's correct. I pulled out the billing records, Your Honor.

THE COURT: All right. Your -- is there anything from the plaintiffs with respect to the motion to move those joint exhibits relative to this defendant?

MS. WAGSTAFF: Nothing, Your Honor, no objection.

THE COURT: All right. Ms. Weiler, your motion will be granted and those exhibits will be admitted into evidence.

(Plaintiffs' Exhibits 61, 62, 63, 64, 65, 66, 67, 68, 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 13, 14, 16, 17, 18, 19, and 20 were received in evidence.)

MS. WEILER: Thank you, Your Honor.

MR. LOVE: One other housekeeping matter, Your Honor.

THE COURT: Yes, sir.

MR. LOVE: I don't want to keep the jury waiting and I can do this at the Court's convenience, but we had three video deposition cuts played with exhibits yesterday. And at some point in time at your convenience I'd like to offer those into evidence.

THE COURT: All right. Let's get the jury and if you will remind me at a break, I'll take care of that, Mr. Love.

MR. LOVE: Thank you.

(Jury returned into the courtroom at 9:05 a.m.)

THE COURT: Good morning, ladies and gentlemen. You can be seated.

Call your next witness, please.

MR. MONSOUR: Your Honor, at this point in time, we would call Dr. Bruce Rosenzweig, our expert urogynecologist.

THE COURT: Sir, would you come up and take an oath or affirmation, please.

(**BRUCE ROSENZWEIG**, HAVING BEEN DULY SWORN, TESTIFIED AS FOLLOWS:)

MR. MONSOUR: Your Honor, at this point in time I've been instructed that I need to ask you to turn on the monitor.

THE COURT: All right.

MR. MONSOUR: Thank you. Your Honor, for some reason

it doesn't seem to be working back there. We've got it right here. Okay. Now it's working. Thank you.

(DIRECT EXAMINATION OF BRUCE ROSENZWEIG BY MR. MONSOUR:)

Q. Good morning.

A. Good morning, sir.

Q. Would you please introduce yourself to the ladies and gentlemen of the jury.

A. Good morning. My name is Dr. Bruce Rosenzweig.

Q. And what kind of a doctor are you?

A. I'm a gynecologist and a urogynecologist.

Q. Okay. We're going to talk about several subject areas today. What I'd first like to do is get a little bit of your background, and then I want to kind of give the jury an idea of some of the things that we talk about. So, first I want to talk about who you are and then I want to give the jury a little bit of a road map of some of the subjects that we're going to be talking about. Okay?

A. Okay.

Q. So, let's talk about your background and training. Where did you get your medical degree from?

A. I went to the University of Michigan for medical school.

Q. Okay. And then you completed residencies and pelvic surgery fellowships?

A. That is correct. I did a four-year residency program which is a post-graduate training in a specific field of

medicine. And mine was in obstetrics and gynecology.
Q. Okay. And it looks like you did a urogynecology and urodynamics fellowship at UCLA Medical School; correct?
A. That is correct.
Q. Is it a fair statement to say that with regard to urogynecology that UCLA is one of the top institutions in the world?
A. That is correct.
Q. Okay. And it also mentions here that you have been a faculty member at the University of Illinois in Chicago.
A. That is correct.
Q. Okay.
A. I --
Q. Keep going.
A. I was an Associate Professor at the University of Illinois. I also ran the residency program. That is the training program that trains young doctors in the field of obstetrics and gynecology.
Q. Okay. Now, are you board certified?
A. Yes, sir, I am.
Q. Okay. And with regard to teaching, what areas do you teach in the field of medicine?
A. Well, I teach medical students, residents, and geriatric Fellows both obstetrics -- or gynecology and also urogynecology.

Q. Okay. Have you published articles -- this case involves stress urinary incontinence and pelvic floor issues. Have you published in that area?
A. Yes, I have.
Q. Have you lectured in that area?
A. Yes, I have.
Q. The publications that you've published, are those publications that are intended for the general public or for surgeons that actually operate in that area?
A. The vast majority of the papers that I've written and also the lectures and presentations that I've given have been directed at the medical community.
Q. Okay. The lectures that you've given fall under the same scope?
A. That is correct.
Q. Okay. Now, if you would give me an idea of -- I know you're here testifying for us today. Can you give me an idea of what your practice right now currently encompasses?
A. I currently see patients approximately two days a week. I do surgery a day and a half a week. And then the rest of my time is doing administrative work and other activities.
Q. Okay. Again, we're talking about stress urinary incontinence. We're talking about polypropylene slings. We're going to talk about polypropylene sling removal. Is this an area that you work in pretty much on a regular basis

every week every day?
A. That is correct.
Q. Okay. We hired you as an expert because of that; right?
A. That is correct.
Q. Okay. And to be an expert for us, did you review material?
A. Yes, that is correct.
Q. And give us an idea of some of the material that you reviewed.
A. Well, specifically I reviewed the medical records of Ms. Blankenship, also deposition testimony of her deposition, treating doctors' depositions. I also reviewed the medical literature.
Q. Okay. And give us an idea of how much medical literature you have reviewed at our request.
A. Well, I've, I continue to review the medical literature just to keep up with medical literature to keep my board certification active.

Specifically, I reviewed studies that relate to the product that we're going to be talking about today, also studies on complications associated with these products, and other studies that we're probably going to be talking about.
Q. And I asked a really poor question and I apologize for it. I said what studies did you read at our request. A lot of the studies you read, you read whether or not you're

working in litigation I would assume.

A. That is correct.

Q. Okay, all right. You don't come here for free. We pay you for your time. Correct?

A. That is correct.

Q. And what do you charge to come testify in cases like this?

A. I charge $10,000 a day for trial testimony.

Q. Okay. That seems like a lot of money. Tell me why you charge that much.

A. I have a busy practice. I have employees. I'm in private practice so that all the expenses of my practice I have to take care of. I have to offer my employees health insurance, a retirement package. And also when I'm not in my practice, I have to have someone that's actually there to cover my practice just in case one of my patients gets sick.

Q. So, instead of testifying this morning, you could in theory be in Chicago operating on revising a sling. True?

A. That is correct.

Q. Okay. So, let's talk about some of the areas that we're going to discuss today. I want to talk to you about stress urinary incontinence and its treatments. Okay?

I want to talk to you about the Obtryx procedure itself. And that's this product right here. Okay? And we're going walk the jury through a video of the Obtryx being

implanted. It's a five-minute video.

I want to talk to you about polypropylene and polypropylene slings. Okay?

Then we're going to follow up with some thoughts on the Obtryx literature. Then we're going to talk about the safety of Obtryx.

And last but not least we're going to talk about Ms. Blankenship. Okay?

A. That's fair.

Q. Does that sound like a fair road map to you for today?

A. Yes, sir.

Q. Okay. So, let me ask you this. Will you agree that the opinions that you give to my questions today will be based upon both a reasonable medical probability and a reasonable medical certainty --

A. Yes.

Q. -- unless you state otherwise?

A. Yes.

Q. Okay. Let's talk -- the opinions that you form today -- let's give the jury a background. The opinions that you form today, what are those derived from?

A. They're derived from my clinical experience and review of the literature.

Q. Okay. So, let's talk -- tell the ladies and gentlemen of the jury -- you are -- in this case you are the first medical

doctor that has testified thus far. And, so, let's give them a background of the injury or the problem, the underlying problem that this case is about. Since you're the first doctor on the stand, I think it would be appropriate for you to explain to them. Please tell us what is stress urinary incontinence?

A. Well, stress urinary incontinence is a medical condition. And with this condition a woman will actually lose her urine when she coughs, sneezes, or does activities that increases the pressure in the abdomen and in the pelvis.

Q. Okay. Is stress urinary incontinence a life-threatening condition?

A. No, it is not.

Q. Okay. Is it a condition that should be downplayed?

A. No, obviously not. I mean, this is a problem that can be a social problem or a hygienic problem. It can alter the way a woman does her activities. It can alter the way she interacts with her family or interacts with her spouse or loved one.

So, it is definitely a, a condition that can have a quality of life impact. But it is not a life-threatening impact on the quality of life.

Q. Okay. What percent of stress urinary incontinence is actually severe?

A. Well, that can be debated, but a good number to hang your

hat on is around ten percent.

Q. Okay. And what would be stress -- what would be, what would be severe stress urinary incontinence?

A. Well, there are a number of things that increase the severity. One is how many times a day you actually leak. Now, obviously, we don't always increase our intra-abdominal pressure and there might be days when you cough more or you sneeze more, but we look at the average number of days that a woman leaks and the average number of times that she leaks. And usually greater than one time a day leaking would make it severe or if there's a significant volume that is leaked.

Q. Okay. There are several different types of treatment for stress urinary incontinence. True?

A. That is correct.

Q. Would you please tell us all what are those?

A. Well, there's basically two ways to treat things. One is behaviorally and one is medically. And the last one is surgically.

Now, behaviorally what we talk about is to avoid things that could cause you to increase your intra-abdominal pressure. So, if you have a chronic cough, have the chronic cough treated. If you have seasonal allergies, treat the seasonal allergies so that you decrease the amount that you're sneezing and, therefore, you can decrease the frequency and maybe the severity of the leakage.

Exercise in general, weight loss in general can decrease not only the frequency and the severity but can also make the, the condition less of a problem for the woman.

There are other things that can, that can be done which are collectively called pelvic floor exercises. A lot of women have been, are familiar with what's called Kegel exercises. So, it's tightening up the muscles of the pelvic floor that actually prevent the urine from going from the bladder through the tube that you pee out of called the urethra and actually comes out. So, those are the non-surgical behavioral therapies.

There are some medicines that can increase the tone of the muscles of the urethra. There -- there are some that we use that might not have -- that we, we feel help but might not be significantly proven in the medical literature. And then the last option is surgery.

Q. Are there different types of surgery to treat stress urinary incontinence?

A. Yes.

Q. And would you please explain those various types of surgery to the ladies and gentlemen of the jury.

A. Well, there are basically three types of, of procedures that have been shown to have probably the best effectiveness, what we call efficacy.

One is the Burch procedure. And this is done through a

small incision above the pubic bone. We don't need to go into the inside cavity of the body where the bowel is and the other internal organs. We stay above this investment that the body has. It's call the perineum. It's like a cellophane layer that protects the internal organs from rubbing against the outside which contains muscles and bones and things like that.

So, we stay above that level called the perineum, use some sutures to elevate the area that is shown to help hold the urine back with increasing pressure in the abdomen. And we bring those up to some of the strong ligaments in the pelvis.

That can be done through, again, a small incision. Yes, that usually requires a little bit longer surgery than some of the others we're going to talk about, a slightly longer hospitalization. And it does take a little bit longer to recover from the operation.

Q. Let me ask you this, though. With regard to that procedure, does that procedure result in any mesh being left behind in a woman's body?

A. No. And, actually, there have been studies that have looked at the question: Do you need to use a permanent suture versus a suture that goes away with time, what's called an absorbable suture? And it really doesn't matter for this procedure. The success rate and the long-term outcome is about the same whether you use a permanent suture or a suture

that will go away with time.

Q. Okay. With regard to the slings that are mentioned there, can you give us an idea of what those are?

A. There is something called the pubovaginal sling. And that is an operation where you're placing a device -- and this -- I'm using the term "devices" as a catch-all. You can use a woman's own, what's called fascia. That's the strong tissue that holds things together.

Tendons hold muscle to bone. Ligaments hold muscle to muscle. And fascia -- they're all made out of the same thing called connective tissue. Fascia invests muscles and kind of holds the, the, a lot of the body together. So, it's kind of the strong wrapping around muscle and sometimes around bone.

And, so, you can take this strong tissue called fascia and use it as a loop that goes underneath the opening of the bladder. And we call that the bladder neck. And that's what goes from the bladder to the urethra. And this can help stabilize that portion of the urethra so that it stops leaking with coughing and sneezing.

That can also be done with a non- -- not using the patient's own fascia, but can be used from a fascia that is obtained by a cadaver. It can also be made out of fascia that is obtained from a, from an animal source. That's usually taking the animal's collagen, preparing it so we get rid of all the extra foreign material, and just put the collagen

together, or it can be used -- you can use a synthetic material.

Q. Okay. And let's talk very briefly about the synthetic materials because we'll get into that a little bit more later. We've got the mid-urethral polypropylene slings, polypropylene obviously not being a natural product or from a cadaver or from an animal. Tell us what that procedure is and how it differs, as briefly as you can, from the pubovaginal slings.

A. Well, basically, it's placed in the mid part of the urethra instead of at the opening of the bladder into the urethra. The idea is that that is another area that helps promote the loss of urine so that when a woman coughs, this stabilizes the middle part of the urethra so that there is a, kind of a knee action that blocks urine from going out of the urethra without actually blocking the urethra all the time.

Q. Okay. Now, here's one of the questions that I would like you to answer for me. If the doctors of America did not have the Obtryx sling to treat women with stress urinary incontinence, would those women still have good, safe options?

A. That is correct.

Q. And they would include these top two procedures. Is that a fair statement?

A. That is correct.

Q. And those are surgical options that they would have?

A. That is correct.

Q. Now, let me ask you this today.

MR. MONSOUR: Ms. Blankenship, would you stand up.

(Pause)

MR. MONSOUR: And I'm only doing this because there's four women and you've got to keep them straight at some point in time.

So, Ms. Blankenship, okay, you can sit down now.

BY MR. MONSOUR:

Q. If Ms. Blankenship came to see you in April of 2009 when her Obtryx was implanted, what procedure would you have done to treat her stress urinary incontinence?

A. My first line of treatment to treat stress urinary incontinence is the Burch procedure.

Q. This one right here?

A. That is correct.

Q. Okay. It's a little longer surgery; correct?

A. That is correct.

Q. Slightly longer hospital stay?

A. That is correct.

Q. But no mesh is left behind?

A. That is correct.

Q. Now, have you done all three of these procedures?

A. Yes, I have.

Q. Okay. And how many surgical procedures have you done in your career to treat stress urinary incontinence?

A. Well over a thousand.
Q. Okay. And, first, how long have you been doing these procedures? I should ask that first.
A. Well, I've been practicing close to 25 years.
Q. Okay. The Burch procedure that you've talked about, is it still within the standard of care recognized as a valid treatment for women like Ms. Blankenship?
A. That is correct.
Q. Okay. Has it been endorsed by various organizations as a valid treatment?
A. That is correct.
Q. We heard a lot about organizations yesterday. Do organizations still support the Burch procedure?
A. That is correct.
Q. What about pubovaginal slings?
A. That is also correct.
Q. So, if -- has the efficacy of the Burch procedure versus the Obtryx -- let's focus on Obtryx first. Has the efficacy of Burch versus Obtryx ever been looked at?
A. I haven't seen any studies that directly compare the Burch procedure with the Obtryx mid-urethral sling.
Q. Okay. Have there ever been any studies that have looked at the Burch procedure versus the, just any mid-urethral sling --
A. Yes.

Q. -- that's made out of polypropylene?
A. Yes.
Q. How did the Burch procedure stack up?
A. Well, there, there have been several long-term prospective studies that have looked head-to-head between the mid-urethral sling and the Burch procedure and they show an equivalent efficacy, meaning, --
Q. Okay.
A. -- meaning effectiveness.
Q. All right. And let's break down, let's break down medical treatments into two facets: Safety and efficacy. Explain what efficacy means.
A. Efficacy is how well something works.
Q. Okay. So, that question is: Does the product cure what it's intended to cure?
A. That is correct.
Q. What does safety mean with regard to a medical product such as a mid-urethral sling?
A. What are the problems that can happen both in the short-term and in the long-term associated with doing a procedure, and also what you use to do the procedure; in this case, a device.
Q. Why should women care about the safety of their products if they're efficacious?
A. Well, everything -- every treatment that we do has some

risks associated with it. In order for the person that is agreeing to any treatment, they need to first know that it's going to be helpful for the treatment that they're going to have. But they also need to know what are the risks associated with it so that the individual person can determine: Are these risks something that I'm willing to accept? Are these risks something that I can live with? How frequently something happens, how severe something happens, how long I might expect this complication to go on, and if I do develop a complication, can it be treated.

Q. So, let me ask you this. Are each of these three procedures efficacious at helping women with SUI?

A. Yes, that is correct.

Q. Does one of them have more long-term complications than the others?

A. That is correct.

Q. Which one?

A. The mid-urethral slings made from polypropylene.

Q. Now, with regard to your Burch procedure that you perform, do you ever see complications of long-term pain?

A. Obviously, every surgery has risks. Most of the risks that we see from surgery are in the immediate post-operative period. And what -- when I talk to a patient about the risks, obviously I'm going to tell them that they're going to have pain. They're going to have a risk of infection. They might

have a risk of having difficulty emptying their bladder in the short-term after a procedure.

Regarding long-term pain, it happens exceedingly rarely with my Burch procedures.

Q. Okay. Have you treated women that have had mid-urethral polypropylene slings implanted in them down the road years after their surgery?

A. That is correct.

Q. In the long-term what are you seeing with those women?

A. Well, not only do I have from my clinical experience dealing with these complications which I started to see in the mid 2000s, so I've been seeing these patients for close to ten years now. But also what we're seeing in the literature is that there are a growing number of problems with polypropylene mid-urethral slings that start to show up in a longer term after the procedure than just the normal post-operative period.

So, I'm seeing women that are coming in two, three, four, five, six, seven years after the procedure with a new problem that they didn't have before the procedure, immediately during the procedure, and in what we would consider the normal post-operative recovery time.

Q. And that's -- I guess that's what I'm getting at. Okay? Most people have either had or know someone that's had a surgery in their life. And following the surgery for a few

weeks they're in pain and things hurt. Right?
A. That is correct.
Q. Then they heal up. What you're talking about is beyond that time period?
A. That is correct. And it's important because we as doctors when we do a procedure, we expect that a patient is going to have problems and complications in the short-term and immediate post-operative period. And, therefore, when somebody is out six months, we've said, "Well, you're out past that window that we would normally expect you to start having problems."

What starting to see both in my clinical experience and in the literature, that patients are starting to show up one to five years after these procedures with problems. And, in fact, the literature is even showing that 20 percent, or close to 20 percent of women that have had mid-urethral polypropylene slings are starting to develop the complications more than five years out from the procedure.
Q. Twenty percent are developing problems five years after the procedure?
A. That is correct.
Q. Is that -- would you categorize that as concerning or alarming?
A. I would say that's alarming. And, again, this is a woman that has figured that all of the risks that were discussed

before surgery have now passed. And a lot of doctors might assume that this might not be related to the surgery that I did five, six, seven, ten years ago.

Q. If the rate is 20 percent at five years, what's it going to be at ten?

A. Well, we don't know. And what has started to come out, both from my clinical experience and the literature, is that there is no time that we can say that someone that has had a polypropylene mid-urethral sling is outside of the chance of having a complication. There have been complications that have been shown in the literature that have happened 17 years after a mid-urethral sling was placed in a woman.

Q. Do you know what this is?

A. Yes, sir.

Q. What is it?

MR. MONSOUR: Can I approach, Your Honor?

THE COURT: Yes, sir.

THE WITNESS: Thank you. This is how a medical device comes to us in the operating room. It's in a box containing the medical device and another document that's inside which is called the Directions for Use or Instructions for Use. And this is the box that the Obtryx mid-urethral sling comes in.

BY MR. MONSOUR:

Q. So, if we can break down the device, if we can

break down the device -- and I think we have two of them here. Okay? If you'll open yours and I'll kind of open mine and we'll talk through them together.

You've never actually implanted an Obtryx. Is that a fair statement?

A. That is correct.

Q. But you have implanted transobturator mid-urethral slings?

A. That is correct.

Q. Okay. We will talk about how your use started with those and how you stopped using those in a little bit. We will get there. So, let's look at the package. We've got -- it comes in a box and the package has -- I think Mr. Love walked through this. It's got an instruction manual. Mine has two Halo trocars.

A. That is correct.

Q. And I've got the mesh with the sleeve around it; right?

A. That is correct.

Q. What does yours have?

A. Well, I have a different kind of -- we call these trocars or needles. And I'm going to -- we're going to show you a video about how this is actually placed in a female. And this has a sharp end to be able to pierce through the structures of the inner leg and pop through a firm membrane called the obturator membrane.

It has that connective tissue, that fascia that I talked about earlier. On each side is a muscle group. On the vaginal side it's called the obturator internus, meaning internal, muscle. And on the other side it has the obturator externus, or external muscle.

Q. Okay. If you'd bring that one down here --

MR. MONSOUR: What we're going to do is we're going to play a video, Your Honor, and -- we'd like to play a video. Boston Scientific is aware of it. It is Boston Scientific's own instruction video as to how to perform the surgery. It's a little graphic, but it's only five minutes and 21 seconds long. We will walk through it. We will freeze-frame and I will have you diagram how the surgery is performed. Is it okay if he steps down, Your Honor?

THE COURT: Any objection, counsel?

MR. ADAMS: With counsel's representation that this is one of our videos, no objection.

THE COURT: All right, Doctor, you can step down.

MR. MONSOUR: If anyone gets queasy, raise your hand and we'll stop. It is five minutes long. All right.

BY MR. MONSOUR:

Q. If you would -- here, you can use this to point with.

THE WITNESS: Thank you.

MR. MONSOUR: All right, if we can start playing the

video.

BY MR. MONSOUR:

Q. That's Boston Scientific, the Obtryx Transobturator Mid-Urethral Sling System. That's -- that is what was implanted in Ms. Blankenship; correct?

A. That is correct.

Q. And the other --

A. I'll try to talk up so -- I know we're close, but I'll try to project so that you can hear me.

Q. Okay.

A. I'll try not to talk to the screen.

Q. And there's the trocar?

A. Right. We're seeing the different iterations of what the trocars look like. And, again, this is used to pierce through the tissue that I'm going to be showing you in just a minute.

Now, what we're looking for is a hole in the pelvic bone called the obturator foramen. Foramen means window. And you have to find that area. And we're looking for this area right here, which is the sacral part of the window to place this through.

We have nerves over here. It's call the obturator nerve. There are blood vessels. We want to avoid those. We don't want to injure the nerves or the blood vessels. Obviously, if you injure a blood vessel, a patient could bleed. If you injure a nerve, that can cause pain or actually

numbness in the nerve.

Q. Okay. Now, real quick, just so it's clear for everyone, there are two slings that are here. There's one that's kind of more upright and there's one that's more horizontal. Which sling are we talking about?

A. This is called a retropubic sling. It comes out above the pubic bone. That's the bone that your belt sits on. That's the diagram right here.

We're not talking about that sling today. We're talking about this sling that goes underneath this bone right here. That's the arch. That's an important bone because that's where the baby comes through during a delivery. And some women need to have C sections if these bones are too close together because then the baby can't fit through. There's a lot of studies that have shown that there is differences between this arch and the size of this window based on, on ethnicity.

Q. Okay. So, in the literature that might or might not come up, we're going to be talking about two procedures in this trial. This one would be called the TVT-O or the Obtryx procedure; correct?

A. Correct. And this is what we're talking about with the obturator approach going through this window called the obturator foramen. And, so, if I, if I say transobturator or obturator or TO, meaning transobturator, you all know what I'm

talking about.
Q. Okay. And this is what we would call the TVT or the retropubic one?
A. That is correct.
Q. Different approach, different surgery?
A. That is correct.
Q. All right. As I look in this obturator hole in the bone, I see a lot of things going through it. What is present in that obturator hole?
A. Well, this nerve right here is called the obturator nerve and it innervates your inner leg here. And that's very important for you to be able to walk.
Q. All right.
A. There's also blood vessels here that are in red. The veins are in blue. And there actually is a much larger vessel that comes down a little bit further out, but we're going to just concentrate on these for right now.
Q. Okay. So, if we can, let's talk about the -- before we show the surgery, I want you to kind of give an idea with this diagram and with this and with that trocar give us an idea of how it would go in. And then they can see it, not real-time but close to real-time.
A. What we first do is we identify this area. There's a long muscle of your leg called the adductor longus. And that muscle is important for you to be able to bring your legs

together. Adduction means bringing the legs together.

And where the tendons -- it's this bone right here. You rock your finger -- you'll see this in the diagram. You'll be able to identify this specific area. So, you'll see the surgeon make a little X there.

There will be a hole put right here. There will be a cut in the vagina. This is supposed to go in the mid part of the urethra. The average woman's length of the urethra after having had babies is about three sonometers. It's centimeters, but I had a professor that spoke in sonometers and it just kind of clicked. So, I apologize if it's centimeters, but I will try to not go back to my old way of saying it.

So, we make an incision in the vagina. It's about one centimeter below the opening of the urethra which is called the urethral meatus, meaning opening. There is an incision that's made, maybe one to three sonometers, inside the vagina. And then it's tunneled out to try to get as close to that muscle that I talked about on the inside of the obturator foramen called the obturator internus muscle.

From the outside, this passer is placed, curved, and then brought out through the inside of the vagina. There's a little hook here and there's a little loop here. This is actually hooked onto that and brought out through the hole.

Now, you can see that this is a pretty small little

hole and this is a fairly wide piece of tape. On average, this is a little bit over a centimeter wide.

There's a little dilator here that makes this hole a little bit bigger so that this will get through without a problem.

Q. Okay. Is that one of the concerns as this goes through the -- that it could get crinkled up?

A. Well, we're taking a flat piece of tape, trying to put it through a round hole. What can happen -- and, remember, the surgeon can only see this small little window that he's making inside the vagina. The rest of this procedure, as you'll see in the video, the surgeon is blind to what is actually happening there.

When this is all done, you can only see the small window of the tape. There's all this other tape out here that we can't see.

Q. So, let me ask you this. So, when this goes through -- when I'm the doctor and I punch this through here, do I know as I punch it through there whether I've hit nerves or not?

A. No. However, when the -- there are several things that can be done to help minimize the risk. And this has been shown in anatomic studies where they take cadavers and they put them in different, legs in different positions and then actually watch these trocars go through and to see how close you actually get to the nerves.

And when I'm illustrating the video, there's a way to bring the legs back so that the knee is actually pointed towards the head that moves this nerve further away. So, it's very important to get this hip right here flexed to a certain level so that you avoid the nerve injury.

Q. Okay. So, let's keep, let's keep going. You do, you do the trocars through and then you what?

A. Then you advance the tape through the hole that was created so that it gets into the position where this is then the mid part of the urethra.

Q. Okay. And then what do you do?

A. Well, you cut the tab to remove the tab. And that opens up -- it actually separates these two ends of the sheath. This comes off and then you have the sheath, this outer envelope or sheath that can then be removed.

And we'll show on the video that is a very important part of the procedure removing this. And there have been studies that have shown that if you need to pull real hard to get the sheath off, you can actually see the tape stretching. And there have been studies that have been done to say how much stretch actually permanently damages the tape.

You see every time I stretch it, there are little flakes that come off. And these edges right here start to crinkle, what we call fray. It's like wearing a pair of jeans for a long time and the ends of the blue jeans that have been

rubbing on the concrete start to fray. You see strands that are starting to come out.

So, pressure on this will cause it not to bounce back to its normal position. Edges, as you can probably see, those little white things that are coming off, that's the actual part of the tape that is coming off as particle loss. We call that flaking.

Q. Okay, all right. So, you have now pulled the sleeves off. And what, what's the next step?

A. Well, the final step is to do what's called adjust the tension. These devices are supposed to go in tension-free.

Q. Why?

A. Well, it's been shown that if you put it under tension, you increase the risks associated with it. The first risk you might see is that the patient won't be able to urinate or void or pee. So, if I use either of those terms, you know what I'm talking about.

The other thing is that if it's under tension, it can actually make its way through the vaginal tissue and cause what's called a vaginal erosion, or the mesh is extruded or exposed.

Q. All right. Let's walk through the rest of the video.

A. All right. So, this is the bone structures that we're talking about which are called the inferior pubic, which is this area here, ramus, which means arm. This here is the bone

that you sit on.

Now we have a catheter in the woman's urethra which is right here. The doctor is feeling for that adductor longest tendon and is finding that little notch and making an X right there. So, that's the point where we're going to be going through.

And, again, it's fairly easy to find that, that portion by feeling for that tendon, rocking your finger and the tip of your thumb, and your thumb will hit that exact portion, that exact point right there.

Q. Okay. It says here the distance between the needle entry point and the obturator canal is estimated to be three to five centimeters.

A. Well, what they're talking about, this entry point and this nerve right here. And, yes, if the legs are in the ideal position, if this bone right here is in its average angulation, this nerve will be at or around this distance.

However, there have been studies done, again on cadavers, that have looked at if you change the way the legs are, there is a difference in these bones' narrowness. And if there's a difference in the opening of this window, that nerve actually does get, ends up being closer to where the tape goes through.

Q. Okay. Let me ask it this way. Is that another way of saying that this is a one-size-fits-all surgery in a

not-all-one-size-fits-all world?
A. That is correct.
Q. Okay. Now, what's this showing?
A. This is showing the other sling that we talked about that comes out above the pubic bone.
Q. Sometimes referred to as the TVT?
A. That is correct, or the retropubic, behind the pubic bone, mid-urethral sling.
Q. Okay. And then this is showing the Obtryx, transobturator?
A. That is correct. We talked about the various trocars or needles, the various configurations. One is a curved. This one is what's called a helical. So, the surgeon has the opportunity to decide which one of these needle devices they're going to use.

So, now the surgeon is going to be making the incision in the front wall of the vagina. And, again, I apologize. This is going to be the start where it becomes a little bit more graphic.

This is the incision that's made in the front wall of the vagina. The doctor is taking a pair of surgical scissors and cutting between the vaginal wall and the deep tissue of the vagina to create the plane for the needle to come through, making a stab wound in the inner thigh. And now it's going to pass the needle from the inner thigh through the vagina.

On average, this needle is going through four muscle groups.

Q. Okay. I have a quick question. I've watched this video before. As they're pushing the video -- as they're pushing the trocar through the tissue, I notice there's kind of a pop. What is that?

A. Well, that is where it's actually going through those two muscle groups that I talked about, the obturator internus, the obturator externus, and that fascial window. So, those are two of the muscle groups that the tape is going through.

The other two muscle groups are in the inner thigh. It can go through the adductor brevis, which is one of the smaller muscles that help work your legs, and the gracilis muscle that kind of drapes down along the inner thigh.

Q. Okay. The fascia, can you give us an idea of what the fascia is again?

A. Well, what we've talked about is fascia invests something. It's a protection. I talked about the cellophane on the inner wall that kind of holds all the bowels in and allows them to move around smoothly.

This is thicker than that. It's more heavy. It's kind of like the gristle on a piece of steak. And, so, you can feel that if you're trying to cut through that. There's some meat to that.

Q. So, it's tougher?

A. It is much tougher, yes.
Q. Okay.
A. You'll see this is going through the inner thigh. And now we're seeing that there is some force that needs to be directed to the needle to get it to go through the muscle groups and the fascial window you saw right there, that pop.

So, there was the force that needed to be taken. Bring it out through the incision that was made inside the vagina. You hook the little loop I showed you inside the end of the needle. And then it's brought through.

Now, as you see, there's a little bit of force that it needs to take to get this big piece of tape through the small opening that was made by the needle. That puts tension on the tape. It puts tension on the outer sleeve. But the tape is inside the outer sleeve and it's going to put tension on that area too.

Now, the other side is being brought --
Q. I think this is actually a different trocar.
A. That is correct. This is the curved trocar. And there is a pop and it's going through muscle, the fascia.

Now what's happening is what's called a cytoscopy where a device called a telescope is being placed through the urethra into the bladder to look at both of the structures to make sure that nothing has been injured.

Now the device is being seated into its proper

location. An instrument is being placed behind it to help when the sheaths are coming off not to put any tension on the tape.

Q. Now, why don't you want tension again? Because it will cause the fraying?

A. Well, that's one of the things that can cause the fraying. It can cause -- when the sheaths are coming off, you're putting tension on that. You can get fraying. You can get the sling itself to deform or change its shape, or it can end up being placed with too much tension. And we talked about before that can lead to, in the short term, problems such as difficulty emptying or working its way into the vagina.

Q. Okay.

A. We're going to talk about a different phenomenon later on which meets the longer term problems associated with this actually contracting and shrinking.

Now, you see that you need a little bit of force to take off the outer sheaths. And there have been studies that have actually looked at that as being a very critical portion of this procedure to get the sheaths off without putting a lot of pull on it to get it out through the hole.

Q. Okay. What are they doing here?

A. Right now they're cutting the excess tape off. This is about 40 to 50 centimeters long. When it's all done, about 15

centimeters is left inside the body.
Q. Okay. So, if you'll hold that up again. So, if we hear about somebody having a small portion of their mesh removed, the remainder of this would still be inside the body?
A. That is correct.
Q. Okay.
A. So, the excess is cut. These small holes are closed off. And then suture material is used to close up the vagina.
Q. And then there's one last slide. There's one last little portion here I want to see. And it says here -- it says, "Refer to package insert provided with product for complete Instructions for Use, including indications for use, contraindications, potential complications, warnings and cautions."
Is that correct?
A. That is correct.
Q. And that's this. And that is this that we looked at right here, the Instructions or Directions for Use?
A. Yes.
Q. Okay, all right. You can take your seat.
A. Thank you. Your Honor, may I approach?
THE COURT: Yes, sir.
BY MR. MONSOUR:
Q. So, have you ever used a polypropylene sling to treat a woman for stress urinary incontinence?

A. Yes, I have.
Q. Okay. When did you first do it?
A. Around 2003 I started using the retropubic polypropylene mid-urethral slings.
Q. So, 2003. And did you ever start using the transobturator slings kind of like we just saw?
A. Yes. I was invited to go to Belgium and work with one of the inventors of a transobturator sling. I spent three days there doing lectures, cadaver dissections, and actually placing two of the obturator slings in live patients.
Q. And when was that?
A. That was in October of 2004.
Q. And the man that you learned from in Belgium with regard to transobturator slings, he's pretty highly regarded in that world?
A. That is correct.
Q. Would, would you say that with regard to these types of slings you got some of the best training in the world?
A. That is correct.
Q. So, you started using them in 2003 and 2004. Why are you here?
A. Well, I stopped using mid-urethral polypropylene slings in approximately 2006 to 2007.
Q. And why did you stop using polypropylene mid-urethral slings after using them for about three years?

A. I started seeing patients that were referred to me with mid-urethral polypropylene slings that were having life-altering, life-changing complications.
Q. And you were able to figure this out by implanting women and following them for three years?
A. That is correct.
Q. But did you also get some referrals from some other people too?
A. That is correct. As I stated earlier, I, I had run a residency program where I trained ten residents a year for seven years. Most of those residents stayed in the City of Chicago and still referred me their patients. And, so, I had had a lot of patients being referred to me that started to have problems.
Q. So, what was it about seeing these patients that got you to change your mind on using polypropylene slings?
A. I wasn't seeing the extent, severity, and difficulty treating these complications with the other surgical procedures that I had been doing to treat stress urinary incontinence.
Q. Okay. Have you ever implanted a Boston Scientific sling, whether it was retropubic or transobturator?
A. No, I have not.
Q. Okay. Now, you talk about the complications that are associated with these slings. Give the jury an idea of the

complications that you've seen clinically with women that have come to see you that have had these slings implanted in them.

A. The clinical complaints they come in with are difficulty emptying their bladder, what we call voiding dysfunction; difficulty emptying their bladder completely, which is called urinary retention; pain; pain walking; pain in the pelvis; pain having intercourse; that the mesh actually worked its way through the vagina, the vaginal tissue that you saw in the video that the doctor was closing, and now you see this polypropylene mesh inside the vagina; patients that now have what's called an over-active bladder where they have to go to the bathroom frequently and urgently.

They have what's called irritative voiding symptoms where they have discomfort and they always feel like there's something in their bladder that they have to, to urinate even though their bladder is empty, and also a recurrence of their leaking which was worse than it was before.

Q. One of the things you mentioned was nerve and muscle damage. Can you give us an idea of why a procedure like the Obtryx would cause nerve and muscle damage?

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: I should have objected to this before when he was talking about nerve damage. There's no issue in

this case that Ms. Blankenship, who is the woman who he's here to testify about, she doesn't have any nerve damage. And he's admitted to that. So, Judge Goodwin was very specific saying that they shouldn't be talking about complications that are not at issue with the plaintiff that they're responsible for.

MR. MONSOUR: Except for the fact that other women do have nerve damage, and he's our general causation expert and we're allowed to talk about the complications that these women have.

MR. ADAMS: Judge Goodwin said it's limited to complications this woman has.

THE COURT: Okay. My recollection, counsel, on that particular motion *in limine* may not be consistent with yours.

I find, counsel, that this falls under the motion *in limine* that was filed to preclude any evidence or argument that the pelvic mesh can cause complications not experienced by the plaintiffs. The Court granted that motion. So, my review is not consistent with what you believe the Court's position to have been, Mr. Monsour.

MR. MONSOUR: Well, the -- it's all -- it's kind of all tied together, Your Honor. It's the -- there is shrinkage and then there's the nerves that go in. The nerves are what generate the pain. And all these women have been talking about pain. Well, to have pain, you have to have nerves that transfer the pain. So, they're allowed to talk about chronic

pain. And you can't have transfer of the nerve -- of the pain sensation without a nerve.

THE COURT: They have all indicated -- I agree with you that they suffered pain. He can certainly testify to that. But to those complications or, for lack of a better way of putting it, injuries that might have resulted that these women did not suffer I'm going to preclude as consistent with the Court's order.

MR. MONSOUR: Okay.

MR. ADAMS: The other issue is the only, the only explanation that he has given for Ms. Blankenship's problems -- and, again, that's the only woman who he's addressing -- is shrinkage of the mesh. He hasn't talked about the other things that are on the slide.

And, so, I think counsel -- I should have objected to that earlier. I think counsel should only be talking about whatever his opinions are on shrinkage.

MR. MONSOUR: Shrinkage, degradation, pain. I mean, they're all kind of related. It contracts. I mean, he talks about voiding dysfunction. To try and draw you a picture, you've got the urethra, and the voiding dysfunction is caused by the shrinkage of the sling rising up and pinching off the, the urethra and causing the problem. So, when you say shrinkage or contracture, it's all interrelated.

And then the pain comes from when you cut the sling

where the sling is still, it's up in the obturator area where there are all those nerves. And what is going on, as it shrinks and contracts it's pulling on those nerves. And that's why she has pain.

So, it all falls under this shrinkage, contraction. It's all, it's all related. It's all a part of one process.

THE COURT: I'm not trying -- I will not preclude you from inquiring of him about the pain that they experienced or the genesis of that pain. I'm not going to preclude you from discussing with him the shrinkage and the degradation. I think it's clear from the Court's ruling that he's going to do that. But any type of complication that they did not experience is, in fact, precluded.

MR. ADAMS: And that includes nerve injury. There's no evidence she has nerve injury.

THE COURT: Well, in my opinion, gentlemen, there's a difference between nerve injury and a nerve being pulled which results in pain which is the so-called injury in this case.

MR. MONSOUR: Let me clarify that with him then.

THE COURT: All right. You understand my ruling?

MR. MONSOUR: I, I --

THE COURT: There is a distinction, in my opinion, between nerve injury, which there is no indication that these people, any of them suffered, and what might be related to nerves that cause the pain, which it's clear that they've all

indicated that they suffered.

MR. MONSOUR: Okay. I got you.

THE COURT: All right.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. To clarify my questions from here going forward, when I talk about any sort of nerve issues, what I'm limiting it to, just so it's fair to you and the jury, I'm limiting my questions to the pain that results from the contraction or the shrinkage or the degradation. Okay?

A. I understand that.

Q. Okay. Now, the -- a couple of the things that you mentioned, and I -- some of the things that you mentioned about the problems that we have with this product that you've seen is you've mentioned that it's, it's tough to get it out. It's difficult to remove the product.

A. This is correct.

Q. Why is it difficult to remove these products?

A. Well, there are a variety of things. First is the location that it's placed. The inner thigh has -- and I described during the video that the mesh is going through four muscle groups. To try to dig the mesh out of muscle is very, very difficult. The area where the muscles, that the tape is in the inner thigh is an area that has very large blood

vessels and nerves.

But there's a process that takes place after this polypropylene mesh is placed inside the vagina which contributes to the difficulty in removing the mesh. And what we have here is a description of the four main problems that take place with the mesh.

The mesh degrades, meaning that it gets hard. It gets brittle, and it cracks.

Q. Now, let me interrupt you there. How do you know that it gets hard, it gets brittle, and that it cracks? How do you know that?

A. Not only have I seen this when I have to take the mesh out, but it is very well documented in the medical literature.

Q. Okay. So, as you -- you've seen it physically during a surgery?

A. That is correct.

Q. Okay, shrinkage. Tell us what is shrinkage?

A. I think everyone is aware of if you take a wool sweater, you put it in the dryer, it goes in extra large, it comes out extra small.

What happens with this product is that it sets up a reaction that the body is trying to either get rid of this foreign body, or at least wall it off if you can't get rid of it. It's called the chronic foreign body reaction.

In response to that, there are some blood cells. The

first responder cells are the white blood cells. They go in and they try to get rid of something that's invading the body, whether it's a bacteria or a splinter. The bacteria tries to kill the splinter. It tries to wall it off.

And, so, what happens is these blood cells come together and they form what's called a multinucleated giant cell, which is the white blood cells that come together and try to wall off the individual fibers of the polypropylene from the rest of the body.

If those things grow together, there's no way that any tissue can get in there. And then scar wraps around the whole piece of tape. And that's called a scar plate.

As that scar gets older, it contracts. And, therefore, it causes the mesh to become less wide and less long, which we describe as contraction or shrinkage.

Q. Okay. Is contraction and shrinkage a significant problem for products like the Obtryx?

A. Yes. And as I described during the video that we saw, the idea is that this is supposed to be placed tension-free. And we talked about the importance when we're doing the procedure, making sure that the device is not under tension when we're done with the procedure.

Unfortunately, if contraction and shrinkage takes place, it's then going to put the device under tension. And, therefore, as I talked about how several years after the

device is placed we start to see new problems that showed up that weren't a problem in the immediate post-operative period.

And the reason for that is the device is degrading. The device is contracting and shrinking. There's a chronic foreign body reaction where studies have shown doesn't go away. It's always going to be there, which means that this process is then going to start itself all over again so that there is no time when the device will be, will stop degrading. There is no time where the device will stop contracting and shrinking. And there is no time where this chronic foreign body reaction will stop.

Along with that chronic foreign body reaction is a process of inflammation. If you cut yourself or you burn yourself, the area where the cut is undergoes changes, but the area around it turns red. And red is a sign of inflammation. It's the body's way of getting more blood into that area to help the body heal.

Now, I talked about the first responders that are the white blood cells. The next thing the body does in the long-term is that it sends a send tree out to say, "What's going on with this area of irritation and damage?" And that sensory is the nerves.

And it's been shown that nerves start growing towards the mesh and actually gets inside the little holes of the mesh which are called pores. And nerves grow up to the mesh and it

hits that plate of scarring that I described for you a few minutes ago, and it creates a little tuber of nerves called a neuroma.

And when I was asked what happens when the mesh is taken out is, well, the nerves that have grown through it get cut. The nerves that have grown up against it get cut. And either they immediately start creating pain or then the nerve could go to sleep. When it wakes up, it's now ready to transmit the signal of pain.

Q. Okay. So, let me ask you this.

Can I see the sling? May I approach, Your Honor?

THE COURT: Yes, sir.

BY MR. MONSOUR:

Q. If I look at this sling, there's a lot of little holes in the sling; right?

A. That is correct.

Q. If, if this -- if tissue grows into those holes, scar tissue grows through those holes, is that what holds it in place?

A. Well, the idea is that normal tissue, blood cells, and fat cells are going to grow into those little pores. The pore size of this product is about a millimeter.

It's been shown that if the pore size is around that size, it doesn't allow good tissue to grow into it. It lets those things that I talked about before, the granulomas from

the chronic foreign body reaction --

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: This is -- again, this is not a permissible general causation opinion. There is -- he's offered no opinions in his report about the impact of pore size. He hasn't even examined our mesh. There's no evidence that he has an opinion either in his report or his deposition that pore size has anything to do with Ms. Blankenship. So, the question is why is he talking about it? He shouldn't be.

MR. MONSOUR: All I was trying to get at, Your Honor, was how it's difficult to cut it out because Ms. Blankenship had a very tough procedure to try and cut it out. I can ask him not to go into the pore size issue.

THE COURT: I'm going to sustain the objection to the substance that's been raised by Mr. Adams and if you can rephrase --

MR. MONSOUR: Sure.

THE COURT: -- and direct him even with a leading question to avoid the area and get to where we need to be.

MR. MONSOUR: Gotcha. Thank you.

THE COURT: I want to preserve the plaintiffs' objection and exception.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. What I'd like to focus on, Dr. Rosenzweig, is not so much the issue of adequacy of the pore size but more once -- in explaining to the ladies and gentlemen of the jury that how, whether there's scar tissue in-growth or natural tissue in-growth, why that makes removing something like this so difficult when it's not that hard to put in. Why is it so much more difficult? Is it because of the tissue in-growth?

A. Well, it's because of the scarring around it and also the location where the mesh is.

Q. Is, is it more difficult to cut something like this out of scar tissue once it's degraded and shrunk and deformed?

A. That is correct.

Q. And why is that?

A. Because the body has enveloped it. It's created attachments outside of the normal position where the mesh is. And that becomes very, very difficult to take out.

Q. Okay. Approximately how many times in your career have you attempted to take out one of these when they've degraded, shrunk, deformed, and caused the woman problems?

A. I've done close to 300 removal procedures which are called explant procedures.

Q. Okay. When you do an explant, do you get all this out?

A. It is exceedingly difficult to get, with the obturator

sling, the mesh out of the vaginal portion of the vagina, let alone trying to dig it out of the inner thigh.

Q. Okay. Is it a fair statement to say that when attempting to remove transvaginal mesh the doctors never get it all out?

A. I would say that it is exceedingly unlikely, from both my clinical experience and review of the literature, to get all the mesh out.

Q. In Jean Blankenship's case, this was used. They cut, let's say, off to about here, the 15 sonometers. Her doctor did a revision. What part did he cut out?

A. He tried to cut the middle portion of the sling in the urethra to separate it in the middle.

Q. So, someone like Jeanie Blankenship, if they moved out this little middle portion right here -- is that fair?

A. That is correct.

Q. So, the rest of this still is inside her today?

A. That is correct.

Q. Now, when you remove this small middle part, does that stop the foreign body reaction, the shrinkage, and the deformation? Does that stop that from occurring on the rest of the sling?

A. No, it doesn't. And, actually, what can happen is -- because now you've re-exposed the mesh to bacteria, that process can start all over again.

Q. So, what is the outlook for women that still have this

inside of them even if they've had a surgery?
A. Well, the processes that we have outlined up there don't stop. They will continue through the life that the, of the mesh inside of a woman.

On average, we're looking at 35 years that these products are going to be in a woman's body. And these processes are going to continue, and the problems that they create, the pain, the difficulty voiding, the pain with intercourse, the problems with irritation, with peeing, and the others that we've talked about are going to continue.
Q. Okay. So, let me ask you this. A woman comes to see you. She went to see another doctor. He put a sling in her. He can't fix it. You're the guy in Chicago that they send the problem people to. You attempt to remove the sling but you can't get all the mesh out. You can only get out a little bit like in Ms. Blankenship's case. And the woman is still having problems. In that situation, what do you do to try and help her?
A. Well, there are a number of non-surgical things that we can do. There are medications that can be placed inside the vagina, a suppository, a Valium which is a nerve modulator and a muscle relaxant. There is physical therapy to try to ease the problems that the muscles are having with where the mesh is going through.

There are nerve blocks which can block the nerves that

are supplying the vagina to try to decrease or mitigate the pain that a woman is having, the pain with intercourse.

And, finally, blocking what's called a trigger point. The mesh is going through a muscle. And that, that becomes a fulcrum of pain that spreads out through the muscle and will cause the pelvic floor muscles to spasm. And that's been described in Jeanie Blankenship currently, that she's got spasm of her pelvic floor muscles.

Where the mesh is going through the muscle is often a trigger point, the fulcrum, the epicenter of that wave of muscle spasm that causes pain. And that point can be injected with medication to relieve it as a trigger point.

Q. Okay. Do long-term -- do the women that have mesh inside of them that have had complications, the women that have the problems that are seeing doctors like you, how do they do long-term?

A. Well, even with the removal operation to treat difficulty voiding, pain, pain with intercourse, there are a group of women, and I would say from the literature and my clinical experience about 20 percent don't get better. About another 20 -- 40 percent get improved, but that improvement can be anywhere from a little bit to a lot. And, actually, only 40 percent actually get better where they're not having a problem.

Q. So, if we look over at Ms. Blankenship right now and she

has already had surgery to put it in. She's already had the surgery to try and fix it. She's not better. How long can someone like Jeanie hope to deal with these problems?

A. Well, as I stated before, the causes of the problems that Jeanie Blankenship was having are going to continue. The degradation, the contraction, the chronic foreign body reaction, chronic inflammation are going to continue. And, therefore, that is what's leading to the discomfort that she's having and that will continue.

Q. All right. I want to talk to you specifically about shrinkage.

THE COURT: Counsel, before you move to a different area, would this be a good time for a break?

MR. MONSOUR: Yes, it would, Your Honor.

THE COURT: Ladies and gentlemen of the jury, I'm going to give you a recess. While you're out, do not discuss this case among yourselves or permit anyone to discuss it with you or in your presence. And please be in your jury lounge at 10 minutes till the hour. We'll stand in recess.

(A recess was taken from 10:33 a.m. until 10:51 a.m.)

(The Jury entered the courtroom at 10:51 a.m.)

COURT SERVICES OFFICER: All rise.

THE COURT: Mr. Monsour.

MR. MONSOUR: Thank you, Your Honor.

BY MR. MONSOUR:

Q. I want to talk to you now about shrinkage of the mesh, but I want to talk about it in a different angle.

If I look at the how-to booklet that we got out of our box, and if we look at the video, one of the things that the video stressed and that the instruction manual stressed, on Page 4, it said, "The user should note the importance of placing the mesh without tension under the mid-urethra." Okay?

A. Yes.

Q. All right. So here's my question. This is a tricky one. If you put the mesh in without tension and you do it right, but down the road it shrinks and contracts, isn't that going to cause tension?

A. That is correct.

Q. So how is a doctor supposed to put this in without tension if the product over time shrinks?

A. Well, since we don't know how quickly it shrinks, we don't know to the extent that it shrinks, it would be very difficult, if not impossible, to be able to put it in in the manner where it will stay tension-free for the rest of a woman's life.

Q. Well, if it shrinks, shouldn't they tell the doctors in here that it shrinks, if they know it?

MR. ADAMS: Objection, Your Honor, with respect to opinions about the DFU. May we approach just briefly?

THE COURT: If you need to.

(The following occurred at sidebar.)

MR. ADAMS: Again, he offered no opinions in his report critical of the DFU. Judge Goodwin didn't discuss this as a general causation opinion. He's not a warnings expert. It's an opinion -- it's a whole area of opinions that were not disclosed.

THE COURT: Mr. Monsour, the question was shouldn't that be in this statement --

MR. MONSOUR: Yes.

THE COURT: -- prior to the objection. In other words, let me say to you that it is definitely a criticism of the DFU.

MR. MONSOUR: Well, it is, but I can ask him if a physician like him would need that information to implant it and wouldn't he expect it, and if that information was in the DFU, couldn't he have relied upon that to gather that information?

THE COURT: That's the same criticism, if it's not in there, for you to ask if it's in there and if it would have been helpful to him and if he would have relied upon it.

MR. MONSOUR: Okay.

THE COURT: It's still a criticism of it not being there.

I have reviewed again the judge's ruling with respect

to this doctor's testimony. I've also reviewed for the first time his expert report and there are no such criticisms.

I've also listened carefully to his testimony thus far and I don't find that to be one of those opinions that's necessary in order to get to one of the disclosed opinions.

MR. MONSOUR: Okay.

THE COURT: Excuse me.

MR. MONSOUR: Can I ask him this, since he is a medical expert --

THE COURT: I'm sorry.

MR. MONSOUR: That's all right.

THE COURT: Excuse me.

MR. MONSOUR: Not in a criticizing way, but can I just ask him if the DFU contains a warning of shrinkage and contracture, if it is in here? That's not a criticism.

THE COURT: You can, you can ask that question.

MR. MONSOUR: Okay.

THE COURT: Because I think that you are permitted to get into that issue. But as to whether or not he would expect it to be there or it's necessary or whether or not it would have been helpful to him to be there, I find that those are criticisms.

MR. MONSOUR: I gotcha.

MR. ADAMS: Can we just -- I guess short-circuit it. I don't want to keep interrupting, but, as you see,

Mr. Monsour is pretty persistent about coming back to things. I think it's clear there was no opinions that should come in on the DFU, so do you plan on going at it, banging on this issue more than just asking him that question?

MR. MONSOUR: I don't think so.

MR. ADAMS: Okay.

THE COURT: Just so the record is clear, I'm preserving your objection and exception. I'm going to preclude opinions criticizing the content of the DFU. Those opinions have not been previously disclosed, and I think that any response is sufficient to preclude them.

MR. MONSOUR: Okay. And I would probably -- let me short-circuit this. I would probably ask him if shrinkage, contracture or degradation is in here, if there is any warning about it, and then move on.

MR. ADAMS: I think you can just ask him if it's in there, that's it.

MR. MONSOUR: That's what I'm going ask him.

THE COURT: If it's in there.

MR. MONSOUR: Yes.

MR. ADAMS: But not whether --

THE COURT: His point is that asking about a warning, if there is a warning in there about it, given his already testimony about shrinkage and degradation, is, at the very least, Mr. Monsour, an implied criticism, so you are free to

ask him if it's in there and nothing further.

MR. MONSOUR: Gotcha.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. Now, you had talked before about the four major complications: Degradation, shrinkage, and deformation. Do any of those appear in the directions for use as a potential complication?

A. No, they are not.

Q. Okay. Now, let's go back to looking at something like this from an implanting surgeon's perspective.

If -- and I don't know how to say this. If the product shrunk a little bit, might it be okay for them not to warn about it, versus if it shrinks a lot? Do you understand my question?

MR. ADAMS: Objection.

THE COURT: The objection is sustained.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. Would a surgeon want to know --

MR. MONSOUR: Let me rephrase my question. I'm sorry, Your Honor.

BY MR. MONSOUR:

Q. Would a surgeon want to know -- or would the surgeon need to know to implant something to keep it tension-free the

amount that a product shrinks?

MR. ADAMS: Same objection, Your Honor.

THE COURT: That objection, given the phrasing of the question, is overruled.

THE WITNESS: The -- the answer to that question is yes.

BY MR. MONSOUR:

Q. Okay. And tell us why.

A. Well, again, this device is meant to stay tension-free through the life of the woman and the device. If it contracts, it's ultimately going to come under tension, and, therefore, it would be important to know that before you implant it.

Q. Okay. Let's talk about -- and I kind of want to explain the mechanical process of shrinkage, degradation, with regard to voiding dysfunction in someone like Ms. Blankenship over there. So if we could -- I'd like to kind of talk about it, and I'm going to draw a very crude drawing -- law school, not art school -- crude drawing, that shows here is the urethra cutting this way, looking at the hole, the urine would flow through this way, the tube would be coming out here. The sling would be placed underneath. Okay?

A. (Nods head.)

Q. If the sling shrinks, what does it do? Can you, I guess, kind of use this chart, if you can see it, and kind of explain

what the shrinking sling would do?
A. Well, when the sling shrinks, in this diagram, it would move up and closer to the urethra.
Now, in order to impact a woman's ability to empty her bladder efficiently and completely, there are certain things that have to happen. The muscles of the urethra have to relax; the bladder has to contract to accommodate the flow of urine. If there is something underneath the urethra that's not completely obstructing it, it can make it difficult for the urethra then to relax so when the bladder contracts, the bladder empties efficiently and completely. So you don't have to plug up -- it doesn't have to rise up so that the opening of the urethra gets smaller for it to impact the ability of a woman to completely and effectively empty her bladder.
Q. So, if I understand, it moves up, it shrinks up this way, but it irritates it?
A. That is correct. It doesn't allow it to go through the relaxation process that is necessary for the bladder to effectively or completely empty all the urine.
Q. And what happens if it actually pinches the urethra?
A. Well, then it will make the woman actually retain urine, what we call urinary retention, which is the worst form of a dysfunction void.
Q. Okay. I want to move on to the topic of degradation. And, other than what you've seen when you've actually seen it

degrade and little pieces of it fleck off, other than you seeing something like that, visually, and upon explant, have you actually read literature, is it recognized in the literature that polypropylene degrades when it's put in the body?

A. Yes.

Q. And what does the literature say?

A. Well, from back in the '70s, it was shown that very strong acids and a substance called peroxide can actually start the degradation process. In the '80s --

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: Again, this is an area outside his report. You've read his report. He doesn't give opinions about the degradation process. He's not a materials science expert. I wish we could just keep him to his report.

MR. MONSOUR: Except for the fact that Judge Goodwin specifically wrote that he could talk about degradation and this is part of the degradation process.

MR. ADAMS: He said he could talk about degradation with respect to what he's seen in his practice, not about literature and materials science.

MR. MONSOUR: I can pull the literature, the reference to the literature if you would like, Your Honor. It

says literature and his clinical experience.

THE COURT: It does. He goes back to a prior ruling that he's made with respect to this doctor in the Ethicon case and he affirms it here, finding that the doctor's qualified to offer the opinion that vaginally implanted polypropylene mesh degrades based on his clinical experience as well as his -- as well as his -- I'm sorry -- and as is in the scientific literature and academic papers. So it's not based simply on his clinical experience.

MR. MONSOUR: Correct.

THE COURT: And, again, I read this opinion as him adopting and reaffirming his opinion in the Ethicon case.

MR. ADAMS: Okay. I guess the problem that I'm having is I don't have that report from Ethicon but I do have his report in this case and he doesn't talk about it.

THE COURT: All right.

MR. ADAMS: My objection, while Judge Goodwin may have been referring to Ethicon, my objection would be his report in this case doesn't talk about degradation and the process of degradation. He talks about shrinkage and contraction.

THE COURT: All right. I overrule the objection based on the Court's ruling. I also find that the Court's ruling was specific such that it should have put all of the parties on notice that he was referring back to his ruling in

Ethicon. And, for that reason, I'm going to permit him to discuss it.

MR. MONSOUR: Thank you, Your Honor.

MR. ADAMS: Thank you.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. I'm not sure exactly where we were when we parted but let's go back.

Does the literature confirm that polypropylene degrades when it's implanted transvaginally and in the human body?

A. That is correct.

Q. Is the vagina -- Mr. Adams, on opening, got up and talked about how polypropylene had been used in many areas of the body for 50-something years and it helps great.

Is the vagina an area of the body that might treat a polypropylene mesh different than the abdomen?

A. That is also correct.

Q. Explain to the jury why.

A. Well, there are three factors inside the vagina that make the use of polypropylene inside the vagina cause concern:

Number one, it has a very high concentration of nerves. It has one of the higher concentrations in the body.

Number two, it has bacteria. It's virtually impossible to completely remove all the bacteria from the vagina.

And, number three, it produces peroxide. There is a bacteria actually in the vagina that eats the starch made by the cells that line the vagina and creates acids and peroxide.

Q. Okay. If someone were to say the abdomen is the same as the vagina, with regard to mesh, that's just not true?

A. There isn't the same concentration of nerves in the abdomen. There -- it's much easier to clear an abdominal incision to make it sterile for surgery and clear the bacteria, and the abdomen doesn't produce peroxide.

Q. Okay. Peroxide. Is peroxide what's known in the scientific community as a strong oxidizing agent?

A. That is correct.

Q. Now, in light of the fact that the vagina has -- versus the abdomen, more nerves, more bacteria, and peroxide, do you believe that polypropylene is not well suited for implantation transvaginally to treat stress urinary incontinence in women?

A. That is correct. I find it an improper material to be used as a permanent implantation to treat stress urinary incontinence in women.

Q. Was it known that polypropylene degraded in -- with slings, that there was degradation of polypropylene in slings, polypropylene slings, implanted transvaginally prior to the Obtryx being launched?

A. That is correct.

Q. Name me the article.

A. It's a study that came out in 2004 by a doctor named A.C. Wang who followed up 700 patients that had slings. And when they had problems, which is a recurrent erosion, meaning that it eroded through the vagina, and this -- these were difficult to treat, he took the mesh out and looked at it under the microscope and saw fragmentation of the mesh filaments. And his conclusion was that this is not an inert product and that it needs to be looked at, what the long-term implications are, with epidemiologic studies.

Q. All right. And that's a great segue to the next thing we're going to talk about, which is studies.

Previously in this trial Mr. Adams showed a slide of 22 studies that were -- he called them studies that were done on the Obtryx. And he read an editorial that talked about numerous other studies, and he went through that with Dr. Pence. He used that editorial yesterday with Dr. Pence a number of times. The editorial that he talked about was called the AUGS statement. Are you familiar with it?

A. Yes.

Q. Was the AUGS statement a discussion of the Obtryx Sling specifically?

A. No.

Q. Okay. Is it fair to say that it was an editorial that was a generalization?

A. That is correct.

Q. Written by how many people?
A. Five.
Q. Five.
Mr. Adams showed 22 studies, and this is his slide from opening. I will trust him that these are the only ones. Do you know of any other Obtryx studies?
A. No, I do not.
Q. Okay. I don't want to go through these in too great a detail, because if the jury is not sick of me yet, they want want to -- they will be very sick of me soon. So I will attempt to narrow my questioning.
We went through these 22 last night, right?
MR. ADAMS: Objection, Your Honor. May we approach?
THE COURT: Yes, sir.
(The following occurred at sidebar.)
MR. MONSOUR: I'm getting there.
MR. ADAMS: I know, but you don't -- yeah, the studies, and I told Mr. Monsour about it, and he told me he would just talk about the two studies, Ross and Cholhan. And now he's trying to talk about all the studies. This expert didn't -- he has a reliance list of material. It only included Ross and Cholhan. He probably shouldn't have shown that slide. Now he's talking about last night we reviewed these studies. I mean, I'm getting bushwhacked here. He didn't even review these studies, a little here at the time of

his deposition. So how can you -- how can you legitimately say this is fair?

MR. MONSOUR: I've never had anybody object to me using the slide that they showed in opening before and saying that I shouldn't show it to the jury after he showed it to the jury, point one.

Point number two, I'm going to say of these, only five of these were actually published in the journals, full articles that were published in journals, which were the best two. Let's talk about those two. You just interrupted me 90 seconds too soon.

MR. ADAMS: Well, he doesn't even know -- he didn't know that until last night because he never looked at the studies.

THE COURT: It is opinion regarding studies that have not been listed and disclosed and I'm going to exclude it.

MR. MONSOUR: Okay.

THE COURT: He certainly can testify to those studies on which he based his opinion.

MR. MONSOUR: Okay.

THE COURT: And any studies that he's made comment on that he's previously disclosed to counsel. But I would agree, not that anyone can bushwhack Mr. Adams, but I would agree with him that those opinions regarding studies that haven't been disclosed are not permitted.

MR. MONSOUR: Okay, okay.

THE COURT: I preserve the defendant's -- the plaintiffs' objection and exception.

MR. ADAMS: I understand you're going to move on to Cholhan and Ross, correct?

MR. MONSOUR: Yeah.

THE COURT: Okay.

MR. ADAMS: Okay. So take the slide down and we don't have to do anything more about his critique on our studies which was undisclosed. Is that fair?

MR. MONSOUR: Taking my slide down that you think is unfair --

MR. ADAMS: That's fine.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. Would you -- take that down. Thank you.

On that list of studies, I want to focus on two of the studies.

There were -- on the list, there's only one randomized controlled trial; is that a fair statement?

A. That is correct.

Q. Well, maybe. Or, well, maybe Tracan is, but we won't talk about that one.

I want to talk about the Ross study first. I don't want to talk about the other ones. But I want you to tell the

jury, first, I want to start off with the Ross study, and if we could pull it up.

The Ross study is what's called a randomized controlled trial. Correct?

A. That is correct.

Q. And tell the jury why a randomized controlled trial is what's called -- do they call it Level 1 evidence?

A. That is also correct.

Q. Why? Why is that the best type of evidence that someone can use to evaluate a product? Randomized controlled trial, Level 1. Why is that the most important type?

A. Well, first of all, during the randomization process, where no one but a random selected computer-generated list decides what treatment the patient gets, so it eliminates bias. It makes sure that both groups are as similar to each other as possible, so that it eliminates the patient factor. It is determined ahead of time what number of patients you need to have to prove the end point, and you look at things going forward instead of looking at things going backward through the retrospectoscope.

Q. Okay. A friend of mine explained to me one time, he said if you don't randomize it and you were checking for people's ability to run a mile and you put the smokers all in one group and the people that jogged every morning in another, you'd get varying results. Is that fair?

A. That -- that is correct.
Q. That's why you mix them up and send them into two different groups and you randomize it, right?
A. That is correct.
Q. All right. Now, this Ross study, is it authoritative?
A. That is correct.
Q. Is it published in a reputable journal?
A. That is correct.
Q. Have you actually been a peer reviewer for this journal?
A. That is correct.
Q. And the article is the American College of Obstetrics and Gynecologists?
A. The journal is actually called *Obstetrics and Gynecology*.
Q. *Obstetrics and Gynecology*, I'm sorry.

MR. MONSOUR: Your Honor, at this point in time I would like to offer plaintiffs' Exhibit 444, also known as the Ross study.

MR. ADAMS: Your Honor, no objection for use as a learned treatise but I don't think it comes into evidence.

THE COURT: Is that your intended use, counsel, or are you offering its admission?

MR. MONSOUR: I am -- I just want to use it for a demonstrative with the jury at this point in time.

THE COURT: All right. Go ahead, please.

MR. MONSOUR: And I can show it to the jury?

THE COURT: Yes, sir.

MR. MONSOUR: Thank you.

MR. ADAMS: No objection to that Your Honor.

(PLAINTIFFS' EXHIBIT 444 WAS MARKED FOR IDENTIFICATION.)

MR. MONSOUR: Okay. If we can pull up, Evan, the Ross study.

(The document was published to the jury.)

BY MR. MONSOUR:

Q. Now, the first thing I want to do is let's look at the top and it says -- it says, "Transobturator Tape Compared With Tension-Free Vaginal Tape For Stress Incontinence, a Randomized Controlled Trial." Correct?

A. That is correct.

Q. Now, the first author is Dr. Sue Ross. That's why we call it the Ross study. Correct?

A. That is correct.

Q. Now, it's comparing the transobturator tape versus the tension-free vaginal tape. So what two products is it comparing?

A. It's comparing the Obtryx with another sling that we talked about earlier that goes behind the pubic bone.

Q. Okay. And, if you remember, it's comparing the one that goes more this way to the one that goes more up and down. Correct?

A. That is correct.

Q. All right. So if we can go down, and let's look down at the bottom, in the -- right here, it says financial disclosure, and it says, "Dr. Ross and Robert accepted grant-in-aid research funding from Boston Scientific." Do we see that?

A. Yes.

Q. Now, if you go up about three paragraphs in the small italicized print, you see right there, in the second one: Peer-Reviewed funding was received from Alberta Heritage Fund for medical grant. Grant-in-Aid industry funding was received from Boston Scientific. Do we see that?

A. Yes.

Q. And then if we go down to the very bottom of the page, on the left-hand side, you see a date. And it's a little below that. There you go. You see a date from December, 2009, right?

A. That is correct.

Q. Okay. And if we go to the next column at the bottom, before we get into the subject matter, it talks about how it is the type of evidence, Level 1 evidence. All right.

You believe this is a reliable study?

A. That is correct.

Q. Tell us why.

A. Well, first, it is a prospective randomized controlled trial. It has a study methodology which is reliable. It has

a large cohort -- or number of patients in it, 199 patients. They did a statistical analysis ahead of time, which is called a power analysis, and that analyzes the number of patients that you need in the study to be able to show that there is a difference between the two groups and that difference between the two groups is due to different treatment modalities.

Q. Okay. If you would go to the next page, to the highlighted area. And it says, just so we know, to clarify, it says, "Boston Scientific devices were used for all procedures: The outside-in Obtryx Halo mid-urethral sling system was used for transobturator tape procedures." Do you see that?

A. Yes.

Q. All right. Is that was what was used, the Obtryx that was used in Ms. Blankenship?

A. That is correct.

Q. Okay. And I have not looked at which trocar was used in case I get that wrong, but it was the Obtryx procedure?

A. That is correct.

Q. All right. Now, if we go to the next area that I have, Evan, on Page 1290 at the bottom of the left column and the top of the right-hand column.

When discussing the Obtryx, it says -- can you read this for us?

A. However, on vaginal examination, the tape was palpable

for 68 women, or 80 percent, in the transobturator group, and 24 women, or 26.7 percent, in the TVT group.

Q. Okay. Oh, keep going.

A. More women in the transobturator tape group experienced groin pain during vaginal palpation, which came to a 15.3 percent in the transobturator group, and 5, or 5.6 percent, in the TVT group.

Q. This was the first randomized controlled trial ever done by Boston Scientific on the Obtryx, correct?

A. That is correct.

Q. And it notes palpable mesh in 80 percent of the women that got Obtryx.

A. That is correct.

Q. What does "palpable mesh" mean?

A. Well, it means that you could feel it different from what you would expect along the front wall of the vagina underneath the urethra. If there was normal tissue integration, it should not be able to be felt.

Q. Okay. If you would go to the next page, the highlighted area. Would you read this for me?

A. Despite the lack of differences in cure rates between the two groups, it was found on digital vaginal examination that more women in the transobturator tape group had tape that was palpable and experienced groin pain compared to the women in the TVT group.

Q. What does that mean?
A. Well, that means when they pushed on the tape, it hurt them in their groin.
Q. Go to Page 1293. Would you read what the article says here.
A. "In these circumstances, where there is the potential for long-term adverse effects of a procedure, we believe that benefit should be demonstrated before adopting a newer procedure into clinical practice."
Q. In Boston Scientific's own study, they're saying that they should have determined that this was safe before they put it on the market?
MR. ADAMS: Objection, Your Honor, that's leading and it's a mischaracterization.
MR. MONSOUR: You tell me what it says.
THE COURT: The objection to the question is sustained, counsel.
Doctor, you can answer the subsequent question.
THE WITNESS: Well, what they say is that you should show that the benefit outweighs the risk before new procedures are placed on the marketplace.
BY MR. MONSOUR:
Q. And this is in the face of examining the Obtryx data?
A. That is correct.
Q. In Boston's study, randomized controlled trial, done five

years after the product was released on the market?
A. That is also correct.
Q. Go down to the next. And then onto the next page, if you could or -- okay. We will read this. It follows on two pages, Doctor, if you will read this.
A. "The presence of palpable tape is concerning; longer-term follow-up is needed to determine whether this outcome leads to extrusion or resolves over time."
Q. Keep reading.
A. "Until long-term follow up is available from this and other trials, TVT should remain the mid-urethral sling procedure of choice."
Q. So what the article says, the Boston Scientific randomized controlled trial done five years too late, it says, do this procedure; don't do this procedure. (Indicating.) Am I summarizing that fairly for the jury?
A. That is correct.
Q. Ms. Blankenship, the following year, had this procedure, didn't she? (Indicating.)
A. She actually had her procedure in April of 2009.
Q. That same year.
A. That is correct.
Q. I'm sorry. I got my dates wrong.
In your opinion, is this a good study for BSC?
MR. ADAMS: Objection, Your Honor. Vague and

ambiguous.

MR. MONSOUR: Let me reask my question.

BY MR. MONSOUR:

Q. Is this study an endorsement of the Obtryx?

MR. ADAMS: Same objection, Your Honor.

THE COURT: The objection to this question being vague and ambiguous is overruled, counsel.

MR. ADAMS: Also, Your Honor, I will object on foundational grounds, too.

THE COURT: Again, he has indicated that he has reviewed this study. I'm going to overrule the objection and permit the doctor to answer the last question, if he can.

THE WITNESS: This would not be an endorsement.

BY MR. MONSOUR:

Q. Let's go to the Cholhan study. I'm sorry. Would you take it down?

MR. MONSOUR: I'm sorry, Your Honor. Let me lay the foundation for it.

BY MR. MONSOUR:

Q. Are you familiar with the Cholhan study?

A. That is correct.

Q. And it was published in what journal?

A. The *American Journal of Obstetrics and Gynecology*.

Q. Is that an authoritative journal?

A. That is correct.

Q. Have you served -- these two articles were published in two respected journals; is that a fair statement?
A. That is correct.
Q. Are you a reviewer for them? Or have you been?
A. Yes, I have been.
Q. And, as a reviewer, what does that mean?
A. When I get an article to review for publication, my job is to go through the study to look at the methodology, the statistics used, to look at the conclusions that are drawn, to see if this is a paper that is worthy of publication, that will add something to the scientific literature.

MR. MONSOUR: Okay. At this point in time, Your Honor, I would offer Exhibit 270, the Cholhan study, to --

THE COURT: As a learned treatise, counsel?

MR. MONSOUR: Yes, Your Honor.

MR. ADAMS: No objection to that as a learned treatise.

THE COURT: All right.

MR. MONSOUR: The same as before, just to show it to the jury.

THE COURT: Yes, sir.

MR. MONSOUR: Can I go ahead and put it up?

THE COURT: Yes, sir.

MR. MONSOUR: Thank you.

(PLAINTIFFS EXHIBIT 270 WAS MARKED FOR IDENTIFICATION.)

(The document was published to the jury.)

MR. MONSOUR: Do you have a copy?

THE WITNESS: I have what is being shown up on the screen.

MR. MONSOUR: I'll give you a copy just in case.

Your Honor, would you like a copy?

THE COURT: Thank you.

THE WITNESS: Thank you, sir.

BY MR. MONSOUR:

Q. Now, the Cholhan study says -- it's titled "Dyspareunia Associated With Paraurethral Banding in the Transobturator Sling." Is that correct?

A. That is correct.

Q. What is dyspareunia?

A. Pain with sexual intercourse.

Q. Okay. What is paraurethral banding?

A. Feeling bands on each side of the urethra.

Q. Okay. Why am I not supposed to feel bands on either side of the urethra?

A. Well, the intention of the product is to integrate into the tissue so that you don't feel anything along the front wall of the vagina because if you do feel something, that can then lead to discomfort for either the man or the woman during sexual intercourse.

Q. Okay. You talked before about shrinkage, contraction,

and degradation. Is banding associated with those?
A. That is correct.
Q. Okay. So explain how in the vagina banding would take place.
A. Well, when you take a tape that is about 1.1 centimeter wide and it contracts, it's going to get narrower, and that can be felt as a band. When it contracts, it creates more tension and that can be felt as a firm area or a band.
Q. Okay. The author's name is Dr. Hilary Cholhan. It's actually a he, Hilary, correct?
A. That is correct.
Q. Okay. And Dr. Cholhan, if you will look down below the page in the left column, it notes that the study is from 2009, and it notes that Dr. Cholhan is a paid consultant and instructor for Boston Scientific, correct?
A. That is correct.
Q. Okay. Now, if we go up to the top of the page in the summary of the article, under the conclusion, would you read what the conclusion is?
A. "We have identified paraurethral banding as a previously unreported complication of the transobturator sling. Surgeons should be aware of the paraurethral banding and subsequent internal dyspareunia as a potential complication."
Q. As a surgeon, if a product caused banding as a result of shrinkage and contraction, is that something that you would

want to know?
A. That is correct.
Q. Why would you want to know that in treating patients for these problems?
A. Well, number one, if it was associated with symptoms, and symptoms like dyspareunia, where a woman would have pain during intercourse, I would want the patient to know about that, that that was a possibility, to determine if this product was an appropriate product for her.
MR. MONSOUR: If you will go two pages over. And I'm sorry. Evan, if you will go back to the second page, I want to orient the jury, in the middle of the first column on the left, go down about halfway down the page and you'll note where it mentions Obtryx.
BY MR. MONSOUR:
Q. The product that was used in this study was what transobturator tape?
A. The Obtryx tape.
Q. The same tape that was put in Ms. Blankenship, Ms. Tyree, Ms. Wilson, and Ms. Campbell?
A. That is correct.
Q. All right. Now, if we can then go back to the third page, 481, middle column, middle of the middle column, would you read what that states?
A. "Although our study is limited by relatively small

numbers, we believe a 24 percent postoperative dyspareunia rate is concerning."

Q. Okay. If we can go to the next column, Evan.

Would you read from there?

A. This situation may be avoidable, since the transobturator sling arms traverse beneath the mid-urethra directly lateral -- excuse me -- directly laterally toward the medial notch of the obturator foramen.

Q. I think you misread that. I think it said the situation may be "unavoidable."

A. Oh, I thought I said "unavoidable." I'm sorry if it came out "avoidable."

Q. Is an unavoidable consequence of paraurethral banding, which leads to 24 percent of the women having postoperative painful intercourse, is that the type of information that you, as a surgeon, would want to know if you were going to consider implanting this product?

A. That is correct.

Q. And let's go to the conclusion on the last page, and let's see if Dr. Cholhan agrees with you.

A. It is important for the surgeons who perform the transobturator slings to be aware of paraurethral banding and the internal dyspareunia as a potential complication of this procedure.

Q. So you are in agreement with Dr. Cholhan who is a paid

consultant and instructor for Boston Scientific?
A. That is correct.
Q. Now, I want to focus on Ms. Blankenship.
She had what condition that necessitated her having the sling implanted?
A. Stress urinary incontinence.
Q. And it was implanted -- I've got my date here in my handy-dandy notes -- in April of 2009?
A. That is correct.
Q. Okay. I got it wrong before.
If I look through her medical records, she has, I guess the first symptom noted with the sling in January of 2011, about 21 months later. Is that correct?
A. That is also correct.
Q. Now, you had mentioned before long-term studies, randomized controlled trials and the need for long-term studies. I've seen several studies on these products. Many of them are 12-month studies. Do you consider a 12-month study to be a long-term study?
A. No, that would be a short-term study.
Q. Okay. If a study goes out in time --
MR. ADAMS: (Indicating.)
THE COURT: Yes, sir.
BY MR. MONSOUR:
Q. If a study goes out in time long-term and it only looks

at data at one year, that's the only data that it can collect, what's gone from day zero to one year, correct?

A. That is correct.

Q. In looking at a permanent implant like the Obtryx Sling, why would you want data that's collected more than one year after implant?

A. Well, obviously, if you only look at one year, you will only be able to determine what consequences there are of that procedure that will happen in one year.

Q. Okay. Jeanie Blankenship's problems, the first I could find, and I'm sure I'll be corrected if I'm wrong, happened at about 21 months, the first symptom. And I'll write "JB" on there.

Can you use Jeanie Blankenship and give an example as to why she is a perfect example why one-year data is inappropriate for a permanent implant?

A. Well, at one year, she would have been considered a treatment success, that the procedure was efficacious or effective, and that she did not have any complications.

Q. So if we looked at one-year data with Jeanie Blankenship, Boston Scientific and her doctor would say she's a screaming success; fair statement?

A. That is correct.

Q. All right. Now, she notes that she has voiding dysfunction in -- I guess it shows up about a year after her

first -- or it shows up again about a year after she has her first problems in February of 2012, and it's confirmed by urodynamic studies; is that correct?

A. That is correct.

Q. So what does her doctor do to try and help her out?

A. He takes her to the operating room and does a procedure to attempt to release or cut the sling to relieve her voiding dysfunction.

MR. MONSOUR: If you would put up the surgery slide.

Your Honor, I'm sorry. I would like to offer the -- I would like to offer at this point in time, Your Honor, Joint Exhibit Number 18, specifically, Pages 121 and 122.

MR. ADAMS: No objection. It's already been offered by us this morning.

MR. MONSOUR: Oh, all right. And if you would pull this up.

BY MR. MONSOUR:

Q. If we look on this surgery report, the doctor is talking about the surgery, and he says -- can you read this for us, starting with scarring?

A. It says, scarring in the periurethral area both left and right were more prominent on the patient's right side. I could not definitively identify the transobturator tape despite careful dissection and extensive dissection all the way to the proximal urethra.

Q. Okay. What does that tell you as a surgeon that operates in the pelvic floor?
A. That there was a significant amount of scarring that took place around the obturator sling.
Q. Is that problematic for a patient?
A. That is correct.
Q. Why?
A. Well, we saw it in the last two studies that we looked at. This kind of scarring can lead to pain; can lead to groin pain, if it's pushed on; can lead to pain with intercourse. This kind of scarring can also lead to a voiding dysfunction, where the patient might have difficulty effectively emptying her bladder.
Q. Okay. Does that go back to this drawing that I have done before, where it shows the voiding dysfunction and the sling and the contraction?
A. That is correct.
Q. Okay. So, if we keep reading, it notes, would you keep -- would you continue there under "several areas"?
A. "Several areas of scarring with possible mesh was excised and submitted for pathologic examination."
Q. And then down here, if you would.
A. "Estimated blood loss was between 700 and 800 milliliters."
Q. Okay. Let's talk about that. Why does that stand out to

you?
A. That is a significant blood loss. We would call that gynecologic surgical hemorrhage.
Q. Would that be an indicator that this was a very difficult surgery?
A. That is correct.
Q. Okay. Give me a perspective as to how much blood loss 700 to 800 milliliters is, approximate percentage of the blood that's in the body, how much of it was lost during this surgery to cut out a portion of her mesh?
A. The average volume of blood in an average human being is about 5 liters. This was 20 percent or one-fifth of their blood volume -- of her blood volume.
Q. Is that a lot to you?
A. That is significant, yes.
Q. Okay. Now, did this surgery fix Ms. Blankenship and cure her of all the problems that she had?
A. She did not complain of difficulty effectively emptying her bladder after this procedure. She continued, however, to have discomfort and pain.
Q. Okay. Now, if I understand it correctly, the surgeon cut out some of the mesh during this procedure; is that right?
A. That is correct.
Q. So could I safely say something like there and there was cut out? (Indicating.) Or do we know?

A. I don't think we know. I would say that it was probably less than that.
Q. Okay. So maybe it was just cut? (Indicating.)
A. That is correct.
Q. All right. So, now, after the surgery, if just a little area is cut, what remains of all of this mesh that is left inside of Mrs. Blankenship? (Indicating.) What's going on with this mesh, over here, that's still in her?
A. Well, the same process that was going on before, the degradation, the contraction, the chronic foreign body reaction, chronic inflammation, and deformation are going to continue to take place.
Q. Now, she continues to have problems to this day?
A. That is correct.
Q. From the Obtryx mesh that was left behind in her.
A. That -- excuse me.
Q. Correct?
A. That is correct.
Q. And the nature of her problems are what?
A. Well, she currently has what's called levator spasm or pelvic floor muscle spasm. And, in fact, it has gone from a reaction to something that is actually placed inside the vagina to an anticipation of pain with just the anticipation of something that is being placed inside the vagina. This is what we would characterize as more of a centralization of the

pain, where you don't actually need the peripheral response to pain before the patient actually starts reacting to the pain.

Q. So as something approaches, it goes off?

A. That is correct.

Q. How do you know that it's the mesh that's causing these problems that you described? How do you know it's not something else in her past?

A. Well, number one, the mesh is going through the muscle. It's still in the muscle of the transobturator internus muscle. The obturator internus muscle is connected with the pelvic floor muscles that were noted to be spasming on the independent medical evaluation that was done, that noted this pelvic floor muscle spasm and anticipate -- anticipatory pelvic floor muscle spasm.

After reviewing her medical records, I did not see anything that would lead to irritation of the muscle that would lead to pelvic floor muscle spasm except mesh, a foreign body, in the muscles of the pelvic floor.

Q. And that would be through the obturator approach?

A. That is correct.

Q. Let's rule out another -- some other potential causes that I think Boston Scientific might bring up, might try to point the finger somewhere else, so let's talk about them.

From your view of the medical records, did Dr. Lassere just put the sling in too tight?

A. No, he did not.
Q. How do you know?
A. Looking at the operative report, he used an instrument between the tape and the urethra, like we saw on the video, to assure that tape was not placed too tight.
Q. Okay. And if we go and we look at this document, we talked about shrinkage, the concept of shrinkage in the body, of the mesh. Is that a concept that happens immediately or does it take place over time?
A. Well, it usually takes place over time.
Q. Okay. So if the first symptoms that we see of voiding dysfunction are approximately two years after implantation, does that tell you it's not surgeon error but is instead device error?
A. If it was due to the surgeon placing it too tight, her symptoms would have appeared in the normal post-operative period instead of almost two years later.
Q. Okay. I'm going to run through a few others that I believe their expert is going to blame.

MR. ADAMS: Objection, Your Honor, to the mischaracterization.

THE COURT: The objection to that characterization is sustained.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. Let me ask it this way: Do you believe that preexisting endometriosis causes the problems that you state are coming from the Obtryx Sling?
A. No.
Q. How can you rule that endometriosis out?
A. Well, endometriosis usually does not cause muscle spasm unless the endometriosis is in the muscle. So she wasn't complaining of pain and pelvic floor muscle spasm before her sling, and she's also had a procedure to block her tubes. Then I ruled out endometriosis as a cause of her symptoms because the most common way endometriosis happens, and what endometriosis is is when the normal lining of the womb that is shed every month during the menstrual period, and normally comes out through the cervix and the vagina, goes out through the tubes and implants inside the abdomen. So it's -- the most prevalent theory is what we call retrograde menstruation. At a young age, she had her tubes tied, and she never got pregnant, which means that those tubes are blocked and if they're going to block the -- the egg and the sperm from getting together to create a pregnancy, more likely than not, it would also prevent the flow of blood out.
Q. Can you rule out pelvic inflammatory disease as a cause of her chronic pain and dyspareunia?
A. Yes.
Q. How?

A. Well, pelvic inflammatory disease is an infection caused by bacteria that start at the cervix, move their way through the uterus, and then ends up in the tube. And her tubes are blocked.

Also, her pelvic inflammatory disease was treated, and the vast majority of women who had an episode of pelvic inflammatory disease and are treated don't end up with what's called chronic pelvic inflammatory disease, where they have an invalid infection inside their tubes.

Q. How do the urinary tract infections that were mentioned on opening play into this?

A. Well, in -- one of the records from her prior practitioner, that prior practitioner opined that her urinary tract infections are due to sexual intercourse, what is commonly known as honeymoon cystitis, where the active intercourse actually pushes bacteria from the vagina and the far end of the urethra, where the urine comes out, into the bladder, and actually treated her with an antibiotic that she would take after the active intercourse to decrease her urinary tract infections.

Now, her urinary tract infections cause pain and could cause pain with intercourse, but they cause pain and pain with intercourse while the infection is going on. Once the infection is treated, there isn't pain.

Q. Okay. So it's not a permanent problem?

A. That is correct. It is an episodic problem that will resolve with treatment.

Q. Okay. There are some prior conization surgeries and surgery that resulted from them. Is that playing a role in the problems that she's having with the Obtryx Sling?

A. She had abnormal Pap smears in the past, and she had a treatment where a portion of the cervix was removed and cut off, and then the cervix healed. Now, if there is going to be scarring, the scarring is going to be where the surgery was, which is at the cervix. The cervix -- the average length of the vagina is about eight to ten centimeters. The sling is placed within the first one to two centimeters inside the vagina, so we can see that there is a large degree of separation between where the obturator sling is and where her conizations were.

Q. Okay. The site of the sling, do you believe that where there was a revision surgery, that the nature of that revision surgery led to additional scarring which was problematic for Ms. Blankenship?

A. Well, one of her subsequent treating doctors noted that there was lateral scarring in the vagina, and that lateral scarring was not noted before, and so this is probably a continuation of the contraction, the degradation, and the chronic foreign body reaction that we discussed earlier.

Q. Okay. Let's talk about the future for Jeanie. What does

she have to look forward to with regard to taking care of the Obtryx mesh that is still remaining in her that is still causing her problems?

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: This is another undisclosed opinion. You've read his report. He doesn't talk about future care and treatment of Ms. Blankenship.

THE COURT: All right.

MR. MONSOUR: It talks about that she has a permanent problem so it's -- and I believe they asked him about it in his deposition.

MR. ADAMS: He's already testified that she has a permanent problem, but for him now to go into what she's going to have to deal with in the future, additional surgeries, things like that, is unfair. That's what he was now disclosing.

THE COURT: What did the deposition involve?

MR. ADAMS: He did say it was permanent. He said the problems were permanent.

THE COURT: He said that here. Were the treatment options for the future gone into?

MR. ADAMS: Not future surgeries, no.

MR. MONSOUR: I was going to say when we disclosed

that, he said she's going to have a permanent problem, they should have asked, and permanent problem necessarily involves future medical care.

THE COURT: All right. Counsel, I'm going to preclude the opinions. If it's not in his report and has not been gone over in his deposition, I don't think it's appropriate for him to give undisclosed opinions during trial.

MR. MONSOUR: Okay. Let me go --

THE COURT: I preserve any objection and exception for the plaintiffs. Thank you.

(Sidebar concluded.)

THE COURT: Give me a good stopping place, Mr. Monsour.

MR. MONSOUR: How about right now?

THE COURT: All right. Thank you.

Ladies and gentlemen, I'm going to give you a recess for your lunch. While you're out, do not discuss this case among yourselves or permit anyone to discuss it with you or in your presence, and be in your jury lounge at 1:30 this afternoon. We'll start then.

COURT SERVICES OFFICER: All rise. This Court is in recess.

(A luncheon recess was taken from 12:06 p.m. to 1:26 p.m.)

(The Jury returned to the courtroom at

1:26 p.m.)

THE COURT: Good afternoon, you all.

Mr. Monsour.

MR. MONSOUR: Thank you, Your Honor.

BY MR. MONSOUR:

Q. Are you ready, Dr. Rosenzweig?

A. Yes, sir.

Q. Okay. When we stopped for lunch we were talking about the permanent nature of Jeanie Blankenship's problems if you remember that.

A. Yes, sir.

Q. Okay. Does, does Ms. Blankenship still have mesh implanted in her body from the Obtryx even after her revision surgery?

A. That is correct.

Q. Will this obturator-placed mesh continue to give her problems permanently?

A. With a reasonable degree of medical certainty, yes.

Q. Will it resolve on its own?

A. No.

Q. You talked about shrinkage. You talked about contraction. You talked about degradation and flaking. Will that persist as long as the mesh is implanted in Ms. Blankenship?

A. More likely than not, yes.

Q. Is it true of all women that have the Obtryx mesh still in their bodies?
A. That is correct.
Q. Is the transobturator approach with a polypropylene mesh implanted through the transobturator, is that a bad idea?
A. In my opinion, yes.
Q. Is mesh a safe material to be implanted transvaginally in a woman's vagina?
A. No.
Q. Are there other treatment options available for women that have far, fewer long-term complications?
A. That is correct.
Q. This instruction manual, does it warn about shrinkage?

MR. ADAMS: Objection, Your Honor.

THE COURT: The objection is sustained. We visited this several times. Let's move on.

MR. MONSOUR: Okay.

BY MR. MONSOUR:
Q. Does the literature show valid, long-term proof that the Obtryx is safe?
A. No.
Q. To confirm that there is still sling material inside Ms. Blankenship, did you ever look at some pathology?

MR. ADAMS: Objection, Your Honor. I guess we need to approach.

MR. MONSOUR: This --
THE COURT: Come up.
(The following occurred at sidebar.)
MR. ADAMS: Well, --
MR. MONSOUR: It's in his report.
THE COURT: Let me hear what the objection is.
MR. ADAMS: Yes. My objection is it's outside the scope. I don't believe he did disclose this in the report.
MR. MONSOUR: Can I go get the report?
MR. ADAMS: I'll get mine too.
THE COURT: I have it here somewhere. I thought I did.
MR. ADAMS: I'll grab it.
MR. MONSOUR: It's either in the report or in the *Daubert* order. I believe it's in the report, Your Honor.
THE COURT: Mr. Monsour, repeat your question for me.
MR. MONSOUR: "Did you look at any pathology?"
THE COURT: Uh-huh.
MR. MONSOUR: And if you look on Page 6 of the report --
THE COURT: Yes, sir.
MR. MONSOUR: -- Dr. Trepeta's examination found sling material, this right here. It's disclosed.
MR. ADAMS: This witness observed that Trepeta -- Trepeta is going to testify. He didn't make any comments on

the fact that Trepeta did an examination of the pathology. And this witness did not do an examination of the pathology. That was my point.

THE COURT: Don't interrupt each other and let me read, please.

MR. ADAMS: Certainly, Your Honor.

THE COURT: All right. What else? Anything further from either of you?

MR. MONSOUR: Mine is only that it's disclosed and that's what I'm asking him about.

THE COURT: He has disclosed, based on my review of what you pointed to me on Page 6, that he has apparently reviewed Dr. Trepeta's records, including the fact that he noted pathology. He can testify to that. That's, that is, in fact, disclosed.

MR. MONSOUR: Okay.

THE COURT: Your question may seem to indicate that he himself observed some type of pathology. You may want to make sure that your question conforms to the opinion that he does discuss having reviewed Trepeta.

MR. ADAMS: Your Honor, my additional point is, and I think I know Mr. Monsour well enough that now he's going to try to invoke opinions from this witness about whatever Trepeta observed in the pathology. That's -- he doesn't give any opinions about it. He makes the observation that Trepeta

did an examination. So, that's the only thing he can testify about.

THE COURT: I will exclude any opinions. It would seem to me, based on my review of this, that that's one in a number of things that this doctor reviewed in order to formulate his opinions. He's certainly able to testify to that fact.

But, of course, he can't testify to Dr. Trepeta's opinions, but he can testify to what he reviewed, including the fact that Trepeta had viewed pathology which is in support of the opinions that he gives in this report.

MR. MONSOUR: Thank you.

THE COURT: I preserve an objection and exception for the plaintiff to my ruling.

MR. MONSOUR: Thank you.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. Dr. Rosenzweig, did you review some pathology slides that were completed by Dr. Trepeta?

A. I reviewed Dr. Trepeta's report. I did not review the slides themselves.

Q. Did his report confirm the presence of mesh in what was removed from Jeanie Blankenship?

A. Yes, it did.

MR. MONSOUR: I will pass the witness. No further

questions.

THE COURT: Cross-examination, counsel?

MR. ADAMS: Thank you, Your Honor.

(CROSS EXAMINATION OF BRUCE ROSENZWEIG BY MR. ADAMS)

Q. Hi, Doctor. It's Rosenzweig; correct?

A. Rosenzweig.

Q. Rosenzweig, thank you. And you and I have not met before today; correct?

A. That is correct.

Q. And, sir, you are no stranger to the courtroom; correct?

A. That is correct.

Q. And you have been testifying in litigation since 1990; correct?

A. That is correct.

Q. And, in fact, you have given over 200 depositions; correct?

A. I don't know if it's over 200, but probably over 100.

Q. Yeah. Somewhere in the vicinity of 100 to 200 depositions; correct?

A. That is correct.

Q. And when you were being deposed in those instances, you were being paid by one side or the other to act as an expert witness; correct?

A. That is correct.

Q. And today you are here acting as an expert witness;

correct?
A. That is correct.
Q. And the plaintiffs have paid for your time; correct?
A. That is correct.
Q. And you mentioned before that you're -- I think it's about three, three and a half hours of testimony today you will charge $10,000; correct?
A. That is correct.
Q. Now, your 10,000 a day charge, that didn't exist as of May of this year; correct?
A. No, it did, yes.
Q. Well, isn't it true that in May of this year you testified in another trial and your rate was $5,000 a day?
A. Well, that was a pre, before I -- that trial had started or that case had started before my rate had gone up, yes.
Q. Okay. So, but your rate for testifying in trial doubled from $5,000 to $10,000 a day; correct?
A. That is correct.
Q. And, now, given that you've been doing this from 1990 up until now -- now, you have actually -- in your business you have actually created a separate corporation for your litigation; correct?
A. No, I have not.
Q. Well, you have a separate business; correct?
A. No, that is my entire business.

Q. All right. And do you have a particular name that you use for your litigation consulting?
A. No, I do not.
Q. All right. And I know that you testified before that in a given week you will do surgery on about a day to a day and a half; correct?
A. That is correct.
Q. And then you said that you spend about two days, sometimes a little bit more than two days on what you label as administrative time. Is that fair?
A. That is correct.
Q. And the administrative time includes your litigation activities; correct?
A. That is correct.
Q. And isn't it true, sir, that since you have been consulting on mesh litigation, you have billed over $1 million?
A. I don't know what the exact figure is.
Q. Well, you testified before that you billed over $900,000 consulting on mesh litigation; correct?
A. That is correct.
Q. And, so, that testimony was given -- I believe that was given when you -- do you remember my partner who took your deposition, Mr. Keenan?
A. That is correct.

Q. All right. And he took your deposition I think about five months ago. I can get you the exact date. But --
A. I think it was over the summer, but that's probably about right.
Q. Okay. And just so I'm being clear, you're right. It was in June of 2014; correct?
A. That is correct.
Q. And, obviously, you've been working on your consulting work in mesh litigation after June of 2014 all the way up until now; correct?
A. That is correct.
Q. And, so, is it fair to say that you've made approximately a million dollars consulting in mesh litigation; correct?
A. That is correct.
Q. Now, -- Doctor, just for ease of time, I'm going to put -- and I mean you no offense by this. I'm going to put Dr. Rosen [sic] right now. It's -- it is R-o-s-e-n-z-w-e-i-g?
A. That is correct.
Q. Okay. I'll spell it all out. Okay. So, I've written down $1 million mesh litigation. We've already talked about that; correct?
A. That is correct.
Q. Now, Mr. Monsour brought out that yesterday I showed this jury an AUGS statement. And you recall the questions from Mr. Monsour on that?

A. That is correct.
Q. You've seen that statement before; correct?
A. Yes, I have.
Q. And you've been asked questions about it before. I think Mr. Keenan asked you questions about it before; correct?
A. That is correct.
Q. And I don't want to pull it out, but I will if we need to. But you'll agree with me that that is a statement that was issued by five people and then approved by the AUGS Board of Directors; correct?
A. That is correct.
Q. And what does AUGS stand for?
A. The American Urogynecologic Society.
Q. All right. And that is the largest society of professionals like yourself in the United States; correct?
A. For urogynecologists, that is correct.
Q. And that, that statement -- and the jury will recall that -- that it was stated that 99 percent of the members of AUGS use polypropylene mid-urethral slings; correct?
A. That's what it states, but that actually is not what the data shows.
Q. All right. Well, you'll agree with me that that's what it states; correct?
A. That is correct.
Q. And you obviously are in that one percent of people in

your industry that do not use polypropylene mid-urethral slings; correct?

A. Well, sir, that statement is based on a study by Clemons. And what Clemons did in that study --

Q. No, sir. Let's just go back to the statement. Mr. Monsour will be able to ask you questions later.

MR. MONSOUR: Your Honor, I object. He's --

THE COURT: Let me hear this objection. Go ahead, please, Mr. Monsour.

MR. MONSOUR: He asked him a question and he's answering the question. He's not allowing him to complete his answer.

MR. ADAMS: And I would move that his response was nonresponsive and that's why I was rephrasing it, Your Honor.

THE COURT: All right, gentlemen, let's begin again. Ask the question and, Doctor, you listen to it and answer it directly.

BY MR. ADAMS:

Q. Sir, will you agree with me that the AUGS statement states that 99 percent of its members use polypropylene mid-urethral slings; correct?

A. That's what the statement says and it's based on a survey.

Q. All right.

MR. ADAMS: And I move to strike everything except

for "yes," Your Honor.

THE COURT: That motion is denied. The witness, I believe, answered the question and gave his explanation and I believe that's appropriate.

MR. ADAMS: That's fine.

BY MR. ADAMS:

Q. And, obviously, you fall in the one percent. And I don't want to quibble with you about how the 99 is derived. But you're in the one percent, or that group of doctors who do not use mid-urethral slings; correct?

A. Well, it would be important for the jury to know actually how that number was derived so that they could see that I am not in the minority because the study actually threw out respondents who did not use mid-urethral slings in coming up with that 99 percent number.

If you read the study, the methodology excluded respondents that did not use mid-urethral slings or did not do pelvic organ prolapse surgery.

Another thing that they state is only 55 percent of respondents -- of AUGS members actually responded to the survey. And they say that this survey doesn't accurately reflect the opinions of AUGS members at large.

MR. ADAMS: Move to strike as nonresponsive.

THE COURT: You have, Doctor, given your explanation, I believe, prior to directly answering Mr. Adams' question.

So, as we proceed I think it will be helpful to the jury, and certainly to me, if you answer directly and then give an explanation if you believe one is required.

THE WITNESS: I'll certainly do that.

THE COURT: In this instance, you gave the explanation. I do not believe you answered it directly.

THE WITNESS: I would fall into the non-sling users, yes.

BY MR. ADAMS:

Q. Right. And according to AUGS, that would be the category other than the 99 percent that they listed; correct?

A. That is correct.

Q. Which would be one percent; correct?

A. That is correct.

Q. Now, we've already talked about your work as an expert. And you had -- Mr. Monsour had Ms. Blankenship stand up during the examination. Do you recall that?

A. Yes, sir.

Q. And you know Ms. Blankenship lives here in West Virginia; correct?

A. That is correct.

Q. And she went to see Dr. Lassere who is a very well credentialed West Virginia doctor; correct?

A. That is correct.

Q. He's one of your peers; correct?
A. That is correct.
Q. And you're not criticizing any of the work or any of the counseling or any of the decisions that were made by Dr. Lassere in this case; correct?
A. That is correct.
Q. And you know that neither is Boston Scientific's experts criticizing any of the decisions or any of the work done by Dr. Lassere in this case; correct?
A. That is correct.
Q. Now, you have never examined Ms. Blankenship yourself; correct?
A. That is correct.
Q. You had not even met Ms. Blankenship until you came to West Virginia for this trial; correct?
A. That is correct.
Q. The first time you met her or laid eyes on her was this morning; correct?
A. That is correct.
Q. And, so, all of the opinions that you have been giving as a paid expert since 1990 making over $1 million in mesh litigation is basically derived on looking at records and reading depositions; correct?
A. That is correct.
Q. You have not engaged in any type of doctor/patient

relationship with Ms. Blankenship; correct?
A. That is correct.
Q. And you would agree that when you treat one of your patients for stress urinary incontinence, you engage in multiple sessions of counseling and testing; correct?
A. That is correct.
Q. And you are in no position -- and, in fact, you would not criticize any of the process that went on between Dr. Lassere and Ms. Blankenship with respect to the decision that was made to implant an Obtryx sling; correct?
A. That is correct.
Q. And, in fact, now when you've consulted in other litigations -- you've done medical malpractice work; correct?
A. That is correct.
Q. And you'll agree with me that in the majority of the time you have testified on behalf of a plaintiff who is suing a doctor in litigation; correct?
A. That is correct.
Q. And, so, you have been paid before to actually be critical and give testimony just like you're doing today from the witness stand that is critical of a practicing physician. Fair?
A. That is correct.
Q. And, so, practicing physicians include gentlemen like Dr. Bhanot, Dr. Lassere, and Dr. Luby who are busy full-time

seeing patients; correct?
A. That is correct.
Q. Now, when we talk about the doctors, like we'll take Dr. Lassere, have you ever met him?
A. No, I have not.
Q. You haven't talked to him either; correct?
A. No, I have not.
Q. The only thing you've done is to read his deposition. Fair?
A. And his medical records, yes.
Q. Fair enough. So, you reviewed his deposition and his medical records; correct?
A. That is correct.
Q. And you'll agree with me that he was a very well -- or he is a very well qualified doctor in a specialty field; correct?
A. That is correct.
Q. And you have testified before when you are acting on behalf of a plaintiff suing a doctor that doctors have an obligation to keep abreast of the scientific literature that is in their field; correct?
A. That is correct.
Q. That's basic; correct?
A. That is correct.
Q. You learn that in medical school; correct?
A. That is correct.

Q. You learn that every when you do your MCLE; correct?
A. MCLE?
Q. Well, your continuing -- your continuing education; correct?
A. That is correct.
Q. My state calls it MCLE. What does your state call it?
A. It's Continuing Medical Education.
Q. Okay, all right. So, you learn from medical school and then in your practice that you've got to keep abreast of the literature; correct?
A. That is correct.
Q. And that is extremely important if you are a doctor implanting a particular medical device into a patient; correct?
A. That is correct.
Q. And you know that the three doctors at issue, you know -- well, by the way, did you read Dr. Bhanot's deposition?
A. No, I have not.
Q. Did you read Dr. Luby's deposition?
A. No, I have not.
Q. And, well, let's just assume that all three of those doctors had been using mid-urethral slings for a couple of years prior to the time that they treated these ladies in this case. Okay?
A. Okay.

Q. And you know that Dr. Lassere, his experience was that he actually started using mid-urethral slings back in the 1990s; correct?
A. I would not argue with that.
Q. Okay. And the jury's already seen the timeline of sling devices. You will agree with me that the original concept of a mid-urethral sling was actually created by doctors who cut off pieces of mesh and then used them, basically custom cut them and used them in operations; correct?
A. That is correct.
Q. And then what happened is that in like 1998 the TVT was created by Johnson & Johnson or Ethicon and that basically was a custom cut piece of polypropylene mesh; correct?
A. It was actually earlier than that, but that's about correct.
Q. All right. How much earlier then? And I'll take your correction.
A. '96, '97.
Q. Okay. So, '96, '97 the TVT comes out and that is a commercially available product; correct?
A. That is correct.
Q. And that product obviously is lawfully sold and can be used by doctors like yourself who are allowed to write a prescription; correct?
A. You don't have to write prescription for it. It's

actually purchased by the hospital and then you use that. So, the hospital is the one that actually purchases it.

Q. Fair enough. And, so, let's go back to Dr. Lassere. He started using these mid-urethral slings back sometime in the '90s. And the jury will hear his testimony later. But you're familiar with that; correct?

A. That is correct.

Q. And then he used a number of different mid-urethral slings. And then eventually he started using the Obtryx. Correct?

A. That is correct.

Q. And you know that that -- Dr. Lassere, like any doctor, including yourself, has an obligation to keep up on the medical literature regarding the products that they put in people's bodies; correct?

A. That is correct.

Q. And, so, Dr. Lassere -- and, again, I think his deposition reflects this -- he was fully aware of all of the information in the scientific literature about the safety and efficacy of the products that he was putting inside people's bodies; correct?

A. Well, I think that the jury will get to hear his direct testimony.

Q. Okay, fair enough. You believe that a doctor should do that, though; correct?

A. That is correct.
Q. All right. And, so, if Dr. Lassere was doing his job, he would have been keeping abreast of all of the scientific literature on the devices that he put in people's bodies; correct?
A. That is correct.
Q. All right. So, now, you said before -- you were talking about degradation, shrinkage and contracture. Do you recall that?
A. Yes, sir.
Q. Those are the problems that you believe exist with polypropylene mesh; correct?
A. Including deformation, yes.
Q. All right. And let's just talk about degradation, shrinkage, and contracture and we'll come back to deformation in a little bit. Okay?
A. Okay.
Q. Now, you said before that in the 1970s there was literature out talking about the problems of using mesh in people's bodies; correct?
A. No. I was stating that in the '70s was when the basic science research came out about what things, what chemicals like peroxides and acids can degrade polypropylene.
Q. Okay. So, but in the '70s there's information about peroxides and acids degrading polypropylene; correct?

A. That is correct.
Q. And that information is known out in the scientific community; correct?
A. If you look for it, yes, you should be able to find it.
Q. Okay. By the way, all of the articles we've been talking about, and this Cholhan article and the Ross article that Mr. Monsour talked about, those are available in journals for doctors to read; correct?
A. That is correct.
Q. And, so, in particular Ross and Cholhan, those are in the -- isn't it the ACOG journal?
A. Well, yes, the obstetrics and gynecology -- what we call the green journal because it has a green cover on it.
Q. Exactly. And it's the green journal and it's probably one of the most widely read journals by doctors in your field; correct?
A. That is correct.
Q. You would have expected that all of the three doctors that were implanting medical devices and practicing in your area would have been reviewing that journal; correct?
A. That is correct.
Q. And that journal included the Ross article and the Cholhan article; correct?
A. Well, actually the Cholhan article is in the *American Journal of Obstetrics and Gynecology* and that's called the

gray journal because it used to have a gray cover on it.
Q. Fair enough. But the same thing goes true with respect to the questions that we talked about the green journal. It applies to the gray journal. Doctors should read those; correct?
A. That is correct.
Q. All right. And you, sir, you from time to time -- you were talking about your history in dealing with the TVT; correct?
A. Yes.
Q. And when you were dealing with the TVT -- and let me, let me slow down and back up. The TVT is the same device that we've talked about that first came out on the market in '76, '77?
A. Actually, '96.
Q. '96, '97. And when that device came out, it was introduced by Ethicon or Johnson & Johnson; correct?
A. That is correct.
Q. And you've talked about how you've actually used that device; correct?
A. That is also correct.
Q. And you had experience, obviously, before in dealing with sales reps from companies like Ethicon or Johnson & Johnson; correct?
A. That is correct.

Q. Sales reps from time to time will talk to you about the advantage of their products like the TVT; correct?
A. That is correct.
Q. And you'll agree with me that you as a medical doctor would never allow any kind of advice by a sales representative to replace your professional judgment; correct?
A. That is correct.
Q. Because at the end of the day, you are the person that is responsible for making the decision as to whether to guide your patient towards a particular medical device or not; correct?
A. That is correct.
Q. And, so, regardless of what a sales rep tells you, regardless of the information that a sales rep gives you, you're going to do your homework and you're going to make sure that that device is safe and it's effective before you put it in a woman's body; correct?
A. As best you can, yes.
Q. And that's what you did back before you decided to put the TVT in a woman's body; correct?
A. That is correct.
Q. And you started putting the TVT into women's bodies back in 2003; correct?
A. Correct.
Q. And, so, as of 2003, you had done all your homework. You

had looked at the literature. And you were secure in your belief that the TVT was a safe and effective product for the people that you were going to put it in their bodies in; correct?

A. That isn't actually completely correct. I still had some trepidation about it. I initially started using it in replacement for my pubovaginal slings. And I didn't -- we didn't get into this earlier, but -- I think I might have. I used a pubovaginal sling as a rescue operation for women that have severe recurrent stress urinary incontinence that there are very few other alternatives. And I moved to the TVT as a replacement for, to see if it was a good replacement for my pubovaginal slings.

Q. Okay. You talked about trepidation. Did you tell any of your patients back in 2003 before you put the TVT into their bodies that, you know, "I've got a little trepidation about this device that I'm going to put in your body"?

A. That is correct.

Q. You did do that?

A. That is correct.

Q. All right. And did you then inform every single one of those patients after that point in time about that trepidation?

A. I have a very honest discussion with my patients about what is known and what isn't known. I wrote a paper back in

the late '80s, early '90s on the pubovaginal sling. And one of the concerns that I started to have was just that, if there are more complications associated with using a synthetic material and maybe trying to find a better synthetic material to use.

Q. Fair enough. You mentioned papers. You have not authored any articles on mid-urethral slings or polypropylene devices; correct?

A. That is correct.

Q. And you talked about --

A. Yes, that is correct.

Q. All right. So, and let me break that down. You haven't authored any papers on polypropylene mid-urethral slings; correct?

A. That is correct.

Q. And you haven't authored any papers on polypropylene medical devices; correct?

A. That is correct.

Q. Okay. And I'm just going to put "no papers PP devices." Now -- and, so, you're familiar with the peer-review process; correct?

A. That is correct.

Q. And you know that as part of the peer-review process, somebody's opinions have to be reviewed by somebody else to make sure that they are scientifically valid; correct?

A. Someone's opinions or the, the study that is about to be published?
Q. The study.
A. Yes. You look at, you look at their methods that they use, the results to make sure that the methods actually show the results. And then you look at their discussion to see if their conclusions are actually validated by their methodology.
Q. Right. So, if a person writes a paper and they put forth data and then draw conclusions from it, that literature, in order for it to be published, goes through a peer review process where it's reviewed by people. And then ultimately they decide whether to accept it or reject it. Correct?
A. That is correct.
Q. And you have never had any of the opinions that you've given in this courtroom peer-reviewed as part of that process; correct?
A. As part of what process? I haven't published any studies about the opinions that I've been given. So, it wouldn't go through the peer-review process.
Q. Right. That's my simple point. The opinions that you've offered concerning degradation, contracture, and other problems with polypropylene, you've never authored a paper on that and published it in a peer-reviewed journal. Agreed?
A. That is correct.
Q. Okay. Now, we were talking about your use of the TVT.

And you had originally started using the TVT in 2003; correct?
A. That is correct.
Q. And then from 2003 to 2005 you continued to use that product; correct?
A. That is correct.
Q. And you have testified before that during that time period, you implanted approximately 20 TVT devices; correct?
A. Approximately 15 to 20, yes.
Q. Okay. And then from 2005 to 2007 you switched and started to use the TVT-O; correct?
A. Well, I actually did my first TVT Obturator in 2004.
Q. Okay. And you stopped using the TVT-O in 2007; correct?
A. That is correct.
Q. And you implanted 40 to 50 TVT-Os; correct?
A. That is correct.
Q. All right. Now, so, let me draw that out real quickly just so the jury will have that. Okay. I've done my best chicken scratching here. Can you see that?
A. Yes, sir.
Q. Okay. And we've already established from '03 to '05 you did 20 TVTs; correct?
A. 15 to 20, yes.
Q. All right. Let me write that down, 15 to 20. And then from '05 to '07 you did 40 to 50 TVT-Os; correct?
A. That is correct.

Q. All right. And you, sir, when we talk about degradation, shrinkage, and contracture, you are not representing to this jury that you are an expert in material science. Fair?
A. That is correct.
Q. And you have -- obviously, you're a medical doctor and you have a medical degree; correct?
A. That is correct.
Q. That takes a lot of time and a lot of intelligence to do that. Correct?
A. Thank you.
Q. Well, do you agree?
A. Yes, sir.
Q. So, you know that in this case, for example, there are material science experts who actually study polypropylene and how it behaves in the human body; correct?
A. That is correct.
Q. And I believe you indicated that your experience with how polypropylene behaves in the human body, one aspect that you rely upon is the fact that you've actually, according to you, have observed it first-hand when you have done these explants or removals; correct?
A. That is correct.
Q. And, so, you described to Mr. Monsour how when you started doing removals you noticed immediately that the mesh had degraded and shrunk and contracted; correct?

A. I don't know whether it was immediately afterwards, but I noticed changes that were, that it was hard and brittle and cracked, yes.
Q. All right. And, in fact, sir, you have testified before that the first time that you did a mesh removal in 2003, you realized that polypropylene degraded; correct?
A. If I testified to that, that I saw it, that there were cracks in the polypropylene, then, yes.
Q. Okay. So, 2003 you make that observation. And I'll put kind of a little window around there so I'm not holding you to the exact date. But sometime around when you did the first removal you knew polypropylene degraded; correct?
A. No, I made an observation that that was what I was seeing.
Q. And you -- obviously, you were familiar with the literature on polypropylene at that point; correct?
A. That is correct.
Q. And then, sir, you have -- and, in fact, even as, after 2003, shortly after that you did a couple more removals; correct?
A. I've been doing removals since that time, yes.
Q. And you were concerned enough that you've testified before that actually you reported degradation or problems with the mesh to the Ethicon representative; correct?
A. That is correct.

Q. And you actually made the effort to say, "There is a concern that I have with your mesh and I believe it's degrading." Correct?
A. I said that there was a concern with the mesh, yes. And these were the problems that the patients were coming in with.
Q. Okay. But those same concerns didn't stop you from continuing to implant the device in somewhere around 55 to the high end of 70 women; correct?
A. That -- because that understanding was starting to evolve what the problem was, yes.
Q. And, so, this problem that you've talked about about degradation, shrinkage, and contracture, you believe that occurs with all polypropylene mesh; correct?
A. That is correct.
Q. All polypropylene mesh used in any mid-urethral sling is subject to degradation, shrinkage, and contracture; correct?
A. That is correct.
Q. And all polypropylene mesh that is used in mid-urethral slings is defective according to you; correct?
A. That is correct.
Q. And, so, in this case, you're not singling out the Obtryx and saying that somehow the mesh in the Obtryx is unusual or different than the mesh in the TVT or in the MonArc or in the SPARC or in any of the other 62 devices that are out on the marketplace; correct?

A. There are differences in the polypropylene. There are differences in the configuration of the weave patterns or the knitting patterns. There's a difference in density. There's a difference in fiber diameter. There's a difference in pore size. There's a difference in the way the mesh is cut. There's a difference in how it's heat-sealed.

So, yes, there will be differences in there. But my statement is the polypropylene is not suitable for a permanent implantation as a permanent device to treat stress urinary incontinence.

Q. Right. So, regardless of the weave, regardless of the density, regardless of all of those factors that you mentioned, all of the products that consist of polypropylene mesh are defective according to you; correct?

A. That is correct.

Q. And I've written down -- just to be fair, I've written down, Dr. Rosenzweig, all polypropylene mesh -- all polypropylene mid-urethral slings are defective. Fair?

A. That is correct.

Q. And you haven't done any type of study on the Obtryx polypropylene mesh to distinguish it from any of the other meshes used in the mid-urethral slings; correct?

A. What do you mean by study?

Q. Well, can you tell me -- well, let's do this. You'll agree with me that all of the mid-urethral slings that are

currently being used by doctors are macroporous monofilament devices; correct?

A. It all depends on how you define macroporous. According to an old classification by a gentleman named Ahmet who made his classification in the '90s, anything over 75 microns, which is 0.7 millimeters, is macroporous. Some of the newer definitions say that macroporous has to be over one millimeter.

Q. All right. And you'll agree with me that the, the Obtryx is a macroporous monofilament mesh; correct?

A. Its pore size is slightly over a millimeter.

MR. MONSOUR: Objection.

THE COURT: Objection. Go ahead and state it, please.

MR. MONSOUR: I was not allowed to ask about pore size and now he's asking about pore size.

MR. ADAMS: I only asked if it's in the classification of macroporous monofilament.

THE COURT: I sustain the objection. Let's go forward, counsel.

MR. ADAMS: All right.

BY MR. ADAMS:

Q. So, are you, sir, able to tell us how the Obtryx mesh is in any way different than the mesh used in Ethicon's TVT?

A. Well, they both have the same density. There is a difference in the additives that each company puts into their, into their polypropylene.

So, polypropylene isn't just a, a carbon and a hydrogen put together. There are other things that are put in such as antioxidants and stabilizers and plasticizers. There's a difference in the color between the TVT and the Obtryx. One has an additive that gives it a blue color. This is a white color. So, there are differences in the chemical makeup of the polypropylene.

Q. Okay.

A. Another difference is that the center portion is heat-sealed so that the little edges that look like barbs are taken off in the center portion. The TVT is made by either cutting it mechanically where you get the barbed edges or cut with a laser so that you don't have the barbed edges. So, there are a lot of differences between the various products.

Q. And you've been critical of the TVT device because you believe that the cutting of that device induces fraying; correct?

A. That is correct. When you mechanically cut the mesh, the edges actually break off and there's a fraying that takes place.

Q. And you've talked in other settings that that fraying can be dangerous when it's implanted in a woman; correct?

A. That is correct.
Q. Besides fraying, the mechanical cutting on TVT devices can also create particle loss; correct?
A. That is correct. Actually, we saw that today when I was pulling on the, on the Obtryx sling. You could see particles falling off of the mesh itself.
Q. All right. You know that with the Obtryx sling, with that mesh the edges have been heat-sealed; correct?
A. Only in the center four sonometers of the mesh. The rest -- as you can see, you have the edges which are called tangs. Only the central portion of the mesh has been detanged or those little edges have been taken off.
Q. All right. And detanged -- the, the purpose of heat-sealing with the detang is to prevent fraying and particle loss; correct?
A. And one of the ideas is that it makes it less elastic so that it won't rope and curl. That's the thought behind using a laser-cut mesh is that it makes the mesh stiffer. But that actually causes a problem because it increases the erosion and it increases the obstruction due to the, the stiffness of the mesh.
Q. All right. And let's talk about -- it's a good sign when I'm ticking these off, Doctor.
A. That is, sir.
Q. Now, when you did your implants on these women, we've

already established that you did your first removal and saw the degradation in 2003. Do you recall that?
A. That is correct, sir.
Q. And then you go on to implant these devices all through 2007; correct?
A. That is correct.
Q. And you'll agree with me that every single time that you would implant a medical device in a woman's body, you would engage in a risk benefit analysis for that particular situation; correct?
A. That is correct.
Q. And you'll agree with me that that is a very important process that each doctor who is implanting a medical device has to engage in; correct?
A. That is correct.
Q. And you're not here to criticize that process that was engaged in by Dr. Lassere or Dr. Bhanot and Dr. Luby; correct?
A. That is correct.
Q. And you know from Dr. Lassere's deposition that he had a good experience in his patients in using the Obtryx device; correct?
A. That is correct.
Q. In fact, you've talked about problems related to the devices. Dr. Lassere, who we've established who was a -- strike that. Dr. Lassere you know -- we've established in the

1990s he started using the TVT; correct?
A. That is correct.
Q. And sometime --
A. We know it's from the late '90s because we've already established when the TVT first came to the market here in the United States.
Q. I put "late" up there.
A. Thank you, sir.
Q. And we know that -- do you remember the time period in which he moved to the Obtryx?
A. We know the Obtryx was first released in 2004. So, it must have been after 2004.
Q. Okay. So, I'm just going to put post 2004 he uses the Obtryx; correct?
A. That is correct.
Q. And you'll agree with me that Ms. Blankenship was not the first patient that he used the Obtryx on; correct?
A. That is also correct.
Q. And, in fact, he had a history of using that product in his patients a pretty good time before; correct?
A. Well, we know that it was released in 2004, and I think he'll probably testify to this jury exactly when he started using it.
Q. Okay, fair enough. And you'll agree with me that his experience and the results of his patients were excellent

according to him; correct?
A. That's what he says. But, actually, there's a little bit of a problem with using your own personal experience from what we know in the literature.
Q. Well, my question was Dr. Lassere says his experience was excellent; correct?
A. That's what he testified to, yes.
Q. All right. And he said that as far as complications, he had a one percent erosion rate; correct?
A. That is what he said. And, again, if you look at the literature, there are problems with looking at individual physicians' experience.
Q. We will get through this faster --
A. Okay.
Q. -- if you can answer my question.
A. Yes, sir.
Q. He said he had a one percent erosion rate; correct?
A. That is correct.
Q. And he said that Ms. Blankenship has been his only case involving long-term complaints about dyspareunia; correct?
A. That is correct.
Q. I put "one incident of dyspareunia." Do you see that, Doctor? I want to be fair to you.
A. That is correct. I can't see it, but I saw you writing. Thank you.

Q. Okay. And, so, again, based upon Dr. Lassere's clinical experience, you would agree with me that he had every reason in the world to continue using the Obtryx and he did; correct?
A. That is correct.
Q. And, in fact, he even continued to use the Obtryx after he was implanting it -- after he implanted it in Ms. Blankenship; correct?
A. That is correct.
Q. He's performed approximately 50 Obtryx surgeries; correct?
A. That is correct.
Q. And according to him -- now, you talked about the Burch procedure and pubovaginal slings. Do you recall that?
A. Yes, sir.
Q. And the jury's already heard, and I don't want to go through it, but you would agree with me that the AUGS statement and other industry statements talk about the advantages of mid-urethral slings over the Burch procedure or pubovaginal slings; correct?
A. In the short-term, yes.
Q. All right. And according to Dr. Lassere, he believes that mid-urethral slings is superior to the Burch procedure; correct?
A. That is his opinion, yes.
Q. And he's the guy on the ground dealing with Ms.

Blankenship when she's having these severe SUI problems and he's the one advising her; correct?

A. In this case, yes.

Q. And he's doing his best. He's keeping up on the literature and he wants a good result for her. Correct?

A. That is correct.

Q. And, so, the fact that the Burch procedure takes a bit longer in time was of no factor to Dr. Lassere when he's trying to get the best result for his patient; correct?

A. I believe that's something you would have to ask him.

Q. Okay. Well, you'll agree with me that that shouldn't be a factor; correct?

A. No, the long-term complication rate and the success rate should be a factor that's taken into consideration.

Q. All right. Let's talk about the Burch procedure. The Burch procedure that you've done, you'll agree with me that the disadvantage -- when you're comparing mid-urethral slings to the Burch procedure, one of the disadvantages is that the Burch procedure is a longer operation; correct?

A. That is correct. It takes me about 30 minutes to 40 minutes to do compared to about 20 minutes.

Q. All right. And it often involves general anesthesia; correct?

A. That is correct. But it can be and has been described as being done under local.

Q. And often women have to stay in the hospital one to two days; correct?
A. That is correct.
Q. And these doctors -- you know, Dr. Lassere described how he's able to do an implant or a surgery with an Obtryx in about 30 minutes or less; correct?
A. That is correct.
Q. And it doesn't involve a hospital stay; correct?
A. Most of the patients that I see that have had slings spend one night in the hospital, but it can be done as an out-patient, yes.
Q. And it can be done without any type of general anesthesia; correct?
A. That is correct.
Q. And then as far as the recovery time, you've seen it in the scientific literature. It talks about how there are more comorbidities associated with the Burch than mid-urethral slings in general; correct?
A. Comorbidities?
Q. It's more morbidities associated.
A. Because comorbidities are things like hypertension and diabetes.
Q. Okay. You know it involves more morbidity; correct?
A. Short-term, yes.
Q. Okay. And we saw the Obtryx operation. And you, you

know, I'll have to be candid with you. The first time that I got involved in this and I saw that procedure, it, it is kind of gory and I'm not used to it. And you understand that's a common reaction to a layperson; correct?

A. Watching surgery, yes.

Q. Okay. And -- but if I were to come in -- if we were to take the time for me to show this jury -- we can do it, but if I was going to show this jury one of these Burch procedures, we would be showing that the doctor makes an incision or cut on the bikini line; correct?

A. That is correct.

Q. And when you do the Burch procedure, you do an open Burch as opposed to laparoscopic; correct?

A. That is correct.

Q. And, so, in order -- after you make that incision, you have to spread open the area that you are going to operate in; correct?

A. With small retractors, yes.

Q. Okay. And, so, again, to a layperson if we were going to take the time, watching the Burch procedure is not going to be anymore pleasant than watching the Obtryx procedure; correct?

A. More likely than not, yes.

Q. Okay. And the device is the trocars. Now, to a layperson when you're looking at a trocar and seeing it for the first time, it seems a little bit unusual. You'll agree

with that?
A. Trocars look rather archaic and barbaric the first time you see them, yes.
Q. But there's devices, for example, like the Capio device. That's another long device with a big needle that reaches down. You use that in surgery; correct?
A. That is correct. It is a long device, but it has a fairly small needle at the end of it.
Q. Okay. And, so, those devices like trocars, they're used in other surgeries besides implanting of mid-urethral slings; correct?
A. That is correct.
Q. All right. So, it's a common -- not a common, but it's a fairly common surgical tool that is used in other operations besides even a mid-urethral sling; correct?
A. Trocars, yes.
Q. Now, Ms. Blankenship. You'll agree with me that when she went to Dr. Lassere, she was having life-altering conditions from stress urinary incontinence; correct?
A. Life-altering?
Q. Yes.
A. I would say it impacted her quality of life. But when I use the term "life-altering" it means that there is a chance that someone could, could die from it.
Q. All right. So, she had -- you will agree with me that

she had very, let's say, severe important-to-her quality of life issues; correct?
A. It did impact her quality of life, yes.
Q. You read her deposition?
A. Yes, I did.
Q. Prior to -- her SUI got to the point where in 2006 and 2007 she was wearing two to three pads a day; correct?
A. That is correct.
Q. 2008, 2009 there was an increased frequency and quantity of stress urinary incontinence; correct?
A. That is correct.
Q. By the time she was visiting with Dr. Lassere, she was wearing adult diapers from time to time; correct?
A. That is correct.
Q. And she was actually developing irritation which would cause a burning like sensation on her, on her skin from having the wet pads; correct?
A. That is what she described, yes.
Q. And there is no question that she made the decision, along with Dr. Lassere, that she didn't want to live that way anymore and she was willing to consent to the risk of a surgery; correct?
A. That is correct.
Q. And you'll agree with me that Dr. Lassere, who was keeping up on the medical literature and had read the DFU from

Boston Scientific, informed Ms. Blankenship of all of the risks that he knew about from that material; correct?
A. I think that's what he's going to testify to, yes.
Q. And you've talked about that after the operation she has suffered from dyspareunia; correct?
A. That is correct.
Q. He told her about that risk; correct?
A. That is correct.
Q. And she's also had urinary problems regarding urinary retention after the operation; correct?
A. She's got dysfunctional voiding. We haven't seen that she's been retaining urine, but she just has a very -- it takes her a very long time to empty her bladder.
Q. Okay.
A. Her bladder is not emptying effectively.
Q. Dr. Lassere told her about the risks of dysfunctional -- it's actually called voiding dysfunction in the DFU; correct?
A. Correct.
Q. And he actually told her that she may have pain, pelvic pain as a result of this procedure; correct?
A. That is correct.
Q. And all of those risks that he told her about, according to the plaintiffs, have occurred; correct?
A. That is correct.
Q. And she consented in that document that she signed to

accept those risks for the benefit that could occur by having the surgery with the mid-urethral sling; correct?
A. For the surgical consent, yes.
Q. And, now, you're familiar with the process when -- obviously in litigation when a doctor may be sued for a procedure. You've acted as an expert in those cases; correct?
A. That is correct.
Q. Now, when a doctor tells a patient about all of the risks that are associated with a device and the patient consents to the operation and then the patient has one of those exact complications, you'll agree with me that there's no basis for a suit against the doctor; correct?
A. Well, it all depends on -- I mean, just about every complication is known. What becomes important is: Is it a reasonable complication? So that is there some factors that took place during the procedure that made it unreasonable for this woman to have a complication. So that just because it's a known complication doesn't make it a reasonable complication.
Q. Okay. My simple question was you don't believe there's any basis for any lawsuit against Dr. Lassere; correct?
A. In this case?
Q. Yes.
A. No.
Q. And -- by the way, before you came to testify in this

case, you understand that this case involves four women; correct?
A. That is correct.
Q. And those four women were treated by three different doctors who all live right here in West Virginia; correct?
A. That is correct.
Q. And these doctors -- I don't want to cover every single one of them. But you'll agree with me that they are all very well qualified board certified physicians like yourself; correct?
A. I'll make that assumption, yes.
Q. And did you -- when doctors are making a decision about the risks and benefits of a medical device, you would agree with me that their clinical experience is extremely important to them in evaluating the safety of the device; correct?
A. Their clinical experience is important, yes.
Q. All right. And, so, even if there are articles saying, "This medical device is the greatest thing since sliced bread," if you as a doctor are having some complications in your clinical experience in your practice, then you might want to reject what the article says and go ahead and use it; correct? Or go ahead and stop using it; correct?
A. Correct.
Q. All right. And, so, even if there were great articles out about a particular medical device, a doctor has to use his

own clinical experience based upon his patients to ultimately make the call as to whether they're going to continue to use the product; correct?

A. If it can be reasonably assumed that the doctor is going to see all of the negative problems associated with the device.

Q. All right. And when these papers are put together that we've talked about like the Cholhan study that Mr. Monsour asked you questions about, that involved how many patients?

A. Somewhere around 50.

Q. You want to check again? I think it was --

A. Or --

Q. Or 24?

A. 24, yes.

Q. Okay.

A. Thank you.

Q. So, --

MR. MONSOUR: Objection.

THE WITNESS: Well, actually, there were 53 --

THE COURT: Just a second. There's an objection. Let me hear your objection.

MR. ADAMS: If it's a correction on the number, I'm willing to accept it.

THE COURT: Well, we won't know until we hear it. Go ahead, please.

MR. MONSOUR: You got the number wrong.
MR. ADAMS: Okay. Would you tell me?
THE WITNESS: The study actually had --
THE COURT: Just a moment, sir, until we get this resolved.
THE WITNESS: I'm sorry.
MR. ADAMS: I'm sorry. There were 25.
THE WITNESS: Well, 25 in the obturator article. There's 53 total in the study, yes.
BY MR. ADAMS:
Q. So, do you have the study up there, Doctor?
A. Yes, I do.
Q. It says a total of 25 TO sling patients and 28 RP patients; correct?
A. That is correct.
Q. So, Cholhan -- when I say TO, that's the transobturator sling; correct?
A. That is correct.
Q. And we've established that the Obtryx is in the class of devices called transobturator slings; correct?
A. That is correct.
Q. And you've already explained that that's because of the way it's attached through the obturator foramen; correct?
A. That is correct.
Q. And, so, Cholhan was evaluating 25 Obtryx and then the --

comparing that to 28 retropubic slings; correct?
A. That is correct.
Q. And I'll put 28 RP. And you've talked about how Cholhan made some comments concerning this, the safety and effectiveness of the Obtryx device; correct?
A. That is correct.
Q. Now, before you came in to testify, did you calculate or even run some rough numbers as to what the collective experience of these three doctors in West Virginia was with respect to their use of the Obtryx?
A. Before I came in today?
Q. Yes.
A. I think that in your opening slide they had done six or seven hundred.
Q. Okay. And when did you look at my opening slides?
A. Those were provided to me yesterday.
Q. Okay. Provided to you by the plaintiffs?
A. That is correct.
Q. You weren't here, obviously, during the opening statements.
A. No, I was not.
Q. Okay. And, so, you know that they all placed collectively 550 to -- what was the number -- 700 Obtryx slings?
A. That's just a recollection.

Q. Okay.

MR. MONSOUR: Your Honor, can I approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. MONSOUR: Does this mean I get to go into every lawsuit that's been made against every one of these doctor so I can show the complaint profile to adequately come up with a study?

THE COURT: The objection specifically is as to which question, counsel?

MR. ADAMS: It's not an objection I don't think.

THE COURT: Well, it might be if you let me hear it.

MR. ADAMS: Yes.

THE COURT: Go ahead.

MR. MONSOUR: I'm objecting to him going into the -- Judge Eifert already ruled that these doctors talking about things being safe and effective is out. They can talk about all these issues. He is opening a door and I'm giving -- this is more of an alert than an objection. I'm going to want to proceed with every claim that has been made against these doctors collectively since he has opened the door into it. He has opened the door into this. He has opened the door into all the people that Dr. Rosenzweig has examined at every single litigation.

This cross-examination has opened the door so wide

open, Your Honor, that my redirect is going to go into some areas that -- I'm just giving the Court fair warning as to where I'm going to go.

THE COURT: I believe that that's an objection based on Judge Eifert's ruling and based on prior rulings. And I want to hear your response because I am not going to let you guys --

MR. ADAMS: All I was going to do was cover what was on my slide, that they placed 550 Obtryx slings and they had a good experience on it. I don't see what their personal experience has to do with opening the door to lawsuits.

MR. MONSOUR: Here's the problem. These doctors say, "Well, I've got -- I don't have any problems." Well, we've got some 20 plaintiffs. Those 20 plaintiffs will tell you otherwise. And, so, he's talking about basically -- they're proffering information which might not be accurate.

MR. ADAMS: Well, Your Honor, I used this in my opening statement. I mean, it's pretty innocuous they implanted 550 slings and they all agreed they had low complication rates and they had a good experience with the product. Otherwise, they wouldn't have used it.

THE COURT: I'm going to allow you to ask the question. If that's an objection, I overrule it.

MR. ADAMS: Okay.

THE COURT: Go ahead.

(Sidebar concluded.)

BY MR. ADAMS:

Q. Sir, let's go back to where we were. We first talked about Cholhan and then we were talking about the three doctors in West Virginia. You've agreed with me that they collectively implanted somewhere in the vicinity of 500 to 700 Obtryx; correct?

A. That is correct.

Q. And according to all of them, they had low complication rates; correct?

A. That is what they state, yes.

Q. And those doctors believe that the Obtryx is -- one of them referred to it as the gold standard. The others referred to it as the standard of care to treat stress urinary incontinence; correct?

A. That is what they said.

Q. And by low complication rates, they were saying that they were 90 to 95 percent --

MR. MONSOUR: Your Honor, objection. This is improper use of deposition testimony. Now we're just bolstering. We are reading doctors', other -- we are summarizing other doctors' testimony that have not or might not testify. And we don't know what's going to come in. And he's basically just using bits and pieces of depositions. This is completely improper. He's cross-examined him with

other doctors' depositions.

MR. ADAMS: Well, Your Honor, he reviewed my slides, so he's entitled to say whether he disagrees with them, which he hasn't done. He's reviewed and relied upon the deposition of Dr. Lassere for his opinions.

THE COURT: He certainly can testify to any deposition testimony that is the basis of his opinion. Mr. Monsour is correct, however, unless it is used as a basis of an opinion, his reading or repeating deposition testimony is not appropriate.

MR. ADAMS: Okay.

BY MR. ADAMS:

Q. Sir, you would agree with me, to wrap this up, you have no basis to dispute or criticize these three doctors' clinical experience as described by them. Fair?

A. I have no basis to dispute that.

Q. You have -- when you were describing the transobturator process, how that, how the Obtryx is actually placed within a woman, you were talking about various nerves, the pudendal nerve and the obturator nerve; correct?

A. That is correct.

Q. And it's undisputed that Ms. Blankenship does not have an injury to either her pudendal nerve or her obturator nerve; correct?

A. A direct injury?
Q. Yes.
A. No. Irritation, possibly.
Q. All right. You, you would agree with me that there are nerve studies that can be done to determine whether a nerve like the pudendal nerve is damaged; correct?
A. Damaged, yes; irritated, no.
Q. All right. There's actually neurologists that specialize in that area; correct?
A. That is correct.
Q. And you'll agree with me that Ms. Blankenship has not been referred by any of her doctors to a neurologist to determine whether there is any objective findings of nerve damage; correct?
A. That is correct.
Q. You have talked about the risk of erosion. Do you recall that?
A. The risk of erosion in what --
Q. Let me back up. That was a poor question. When you were talking about dangers associated with polypropylene mesh, I believe that you talked about the risk of erosion and extrusion; correct?
A. That is correct.
Q. And you'll agree with me that Ms. Blankenship has never had an erosion or an extrusion; correct?

A. She has not been diagnosed with it, yes.
Q. And you have talked about that this mesh that is within her body is going to continue to degrade and shrink and contract; correct?
A. That is correct.
Q. Now, does -- well, strike that.
MR. ADAMS: Might I approach, Your Honor?
THE COURT: Yes, sir.
(The following occurred at sidebar.)
MR. ADAMS: Okay. What I would -- I was in an area that I felt like I needed to ask you before I asked the question.
THE COURT: Uh-huh.
MR. ADAMS: Here's the issue. As you know, Judge Goodwin said we cannot specifically mention the Lynx. Okay. So, what happened was this woman had her Obtryx cut and then, you know, whatever happened, happened.
She eventually goes ---she eventually went to another doctor who implanted another sling. That happens to be the Lynx. I am not going to mention that it is a Boston Scientific product, but I believe that I'm entitled to go into the fact that she has had additional mesh put in her body which he's agreed is the same type -- he says it's all defective.
So, she's had additional mesh that he believes is all

defective that was implanted in her body after the Obtryx. And there's no way he can say whether any of the damage that she has is a result from this mesh or that mesh.

THE COURT: All right.

MR. MONSOUR: That's incredibly far from the truth. And I was asking my questions -- you remember I was phrasing it with the Obtryx sling. The pain goes through the obturator and he described it very accurately. He stayed away from the Lynx. Judge Goodwin has already been very clear in his ruling. Lynx is out. It's not to come in.

MR. ADAMS: He said I can mention it's a Lynx. I can't mention it's a Boston Scientific product. I'm not going to do it. I'm just going to say she had additional mesh implanted in the same way.

THE COURT: I think that it is in his report, if I remember correctly, gentlemen, when he, --

MR. ADAMS: It is.

THE COURT: -- when he talks about Ms. Blankenship, about the implantation of the second sling. I believe that you should be able to inquire of him on that given the opinions that he's asked.

But given the Judge's rulings, I think that you should be precluded from getting into it being the Lynx. If you want an objection and exception on the record, I'll certainly preserve that for you.

MR. MONSOUR: The only point that I would make, Your Honor, is this report was filed and then the motions *in limine* went through and Judge Goodwin was very clear. This, these additional products we're not allowed to go into just like -- just like every time I want to stand up and say, "You guys have had your Pinnacle product pulled from the market," and that's transvaginal mesh. It's the same, it's the same thing. They're trying to bring in other products. He's trying to open the door to other things. That's going to be bad for this case.

THE COURT: He's not going to bring in the name of the product. But this is a specific causation expert. He should be able to explore with that expert the procedures that Ms. Blankenship has had. But I am going to prohibit you, consistent with the judge's rulings, from going into the fact that it's Lynx or the type of sling.

MR. ADAMS: It is a mid-urethral sling and that's all I'll say it is. I'll not say the brand.

THE COURT: Do not bring up anything outside of that, counsel. I'm going to preserve an objection and exception for the plaintiff. But given that this is a specific causation witness, I find that it is appropriate for him to be able to cover with this witness the procedures that Ms. Blankenship has gone through.

MR. MONSOUR: I would request that he be, he be

required to refer to it as a retropubic sling rather than try and confuse it with another transobturator sling.

THE COURT: Do you have an objection?

MR. ADAMS: I was just going to say it's a mid-urethral sling.

MR. MONSOUR: That's too general and prejudicial.

THE COURT: I don't know, quite frankly, that it is prejudicial, but I think that you should refer to it specifically as what it is.

MR. ADAMS: As a retropubic, which is a class of mid-urethral sling.

THE COURT: That's fine.

MR. ADAMS: Okay.

(Sidebar concluded.)

BY MR. ADAMS:

Q. Now, sir, Dr. Rosenzweig, you talked about how after Ms. Blankenship developed some problems she went to see Dr. Lassere. Do you recall that?

A. That is correct.

Q. And Dr. Lassere then tried to resolve her voiding dysfunction by a procedure where he actually cut the area where the mesh was; correct?

A. That is correct.

Q. And you'll agree with me that Dr. Lassere -- and you've read his deposition and you're relying upon that. Dr. Lassere

has testified that he could not confirm whether there was any mesh located in that area; correct?

A. That is correct. In his operative report, as we read earlier, he said he possibly removed mesh.

Q. Okay. And, so, we know that in our timeline she has the Obtryx placed -- and you're free to look at your notes. She has the Obtryx placed on April 8th of 2009; correct?

A. That is correct.

Q. She has -- according to the records, she had her first report of voiding dysfunction on January 11th of 2011; correct?

A. That is correct.

Q. So, she went a year and several months of not having any problems with the Obtryx; correct?

A. That is correct.

Q. And then she has a report -- strike that. Dr. Lassere attempts to revise the Obtryx by doing the cut; correct?

A. That is correct.

Q. And then after that, Ms. Blankenship develops problems with -- sometime after he cuts the sling, the Obtryx, she develops additional stress urinary incontinence; correct?

A. That is correct.

Q. And, in fact, you know that Dr. Lassere told her that, "If I do this procedure where I release the Obtryx, then there's a high probability that your stress urinary

incontinence is going to come back." Correct?
A. Well, the probability that's quoted in the literature is about 10 to 20 percent.
Q. Okay. And, so, her SUI returned; correct?
A. That is correct.
Q. And just so we're clear, he made his cut on July 11th, 2012; correct?
A. That is correct.
Q. And then the SUI returns after that; correct?
A. That is correct.
Q. Now, after she was treated by Dr. Lassere as a result of her SUI problems, she was treated by another fine doctor in West Virginia; correct?
A. That is correct.
Q. And she then went to see Dr. Capelle; correct?
A. Yes.
Q. And you'll agree with me that she is a very well qualified doctor in this area; correct?
A. That is correct.
Q. You have no criticisms of the care that she provided; correct?
A. That is correct.
Q. She, like Dr. Lassere, and all the other doctors, would be keeping up on the scientific literature about the dangers associated with polypropylene slings; correct?

A. That is correct.
Q. And when we talk about polypropylene slings or mid-urethral slings, we've already established that in this category there's retropubic; correct?
A. That is correct.
Q. And that includes the TVT; correct?
A. That is correct.
Q. The Advantage; correct?
A. That is correct.
Q. And in the category of transobturator slings is the Obtryx; correct?
A. That is correct.
Q. And all those devices are defective, according to our earlier discussion, according to you; correct?
A. That is correct.
Q. And, so, when we go back to our timeline, after the sling was cut and Ms. Blankenship developed SUI again, she was treated by Dr. Capelle; right?
A. That is correct.
Q. And at that point in time, the SUI problems progressed and they got worse; correct?
A. That is correct.
Q. And, so, she actually got back to the point that led her to the Obtryx where she decided, "I don't want to live this way with the urinary problems, the pads and things like that."

Correct?
A. That is correct.
Q. And then she, in consultation with Dr. Capelle, talked about having yet another surgery involving the implant of another polypropylene mid-urethral sling; correct?
A. That is correct.
Q. And, in fact, that mid-urethral sling was placed in Ms. Blankenship on March 18th of 2013; correct?
A. That is correct.
Q. And that device is in the classification of retropubic and transobturator. It was a retropubic sling; correct?
A. That is correct.
Q. So, I'm going to write "MUS paren RP placed." And our date was March 18th of 2013. And let me show you this, Doctor, because my writing is a little messy. I wrote "MUS retropubic polypropylene sling placed March 18th, 2013." Correct?
A. Yes, sir.
Q. You agree with that; correct?
A. That is correct.
Q. And you talk about how long-term this mesh is going to shrink and it's going to degrade and it's going to contract; correct?
A. That is correct.
Q. Well, the same is true of this other mesh that's inside

of her body now; correct?
A. That is correct.
Q. And speaking of that, now, you're aware of the fact from reading the deposition of Ms. Blankenship that some time in around 2011 she first concluded that her problems have to be a result of the Obtryx sling because she saw some ads about problems with slings on the TV; correct?
A. That is correct.
Q. And I don't know the -- I don't recall the exact date, but we've agreed that was sometime in 2011; correct?
A. I, I also don't remember the exact date, but I will take your word for it.
Q. All right. I'm going to write down "2011 ad." And I'll put a little squibble up there. That means approximately 2011 ads; correct?
A. That is correct.
Q. And then I'll put "Slings the problem" and a "B" for Blankenship. Okay?
A. Okay.
Q. All right. And, so, even though after, in her belief, she concluded that the Obtryx had to be the cause of her problems, you would agree with me that she then consulted with Dr. Capelle sometime, a year and a half to two years later in 2013 and then agreed to the placement of a retropubic sling; correct?

A. Yes.
Q. And the mesh used in that retropubic sling, would you agree with me, is very equivalent to the Obtryx mesh; correct?
A. That is correct.
Q. All right. It's a different approach, but it's the same mesh; correct?
A. That is correct.
Q. And, so, long-term would you agree with me that to the extent this mesh shrinks, it degrades, it erodes, you're not going to be able to say whether it's due to the mesh from the Obtryx or the mesh that she consented to receive after seeing the advertisements about problems with mesh; correct?
A. Are you talking about her current symptom of levator spasm?
Q. No. I'm talking about her future problems that you were addressing.
A. The future problems?
Q. Yes.
A. That is correct.
Q. All right. And I mean the future problems that you talked about, long-term pain and issues with the mesh degrading; correct?
A. That is correct.
Q. Bear with me, Doctor. I think -- and ladies and gentlemen. I'm close.

(Pause)
BY MR. ADAMS:
Q. Oh, I just want to talk briefly about pubovaginal slings. You did -- you had talked about -- you do a procedure with pubovaginal slings where you use Gore-Tex; correct?
A. I used to use Gore-Tex. I don't use Gore-Tex anymore.
Q. And for what period of time did you use Gore-Tex?
A. From about 1989 until the early '90s.
Q. Okay. And Gore-Tex -- you'll agree with me that there's never been any type of -- you're aware that there was no randomized clinical trials on Gore-Tex prior to the time that you used it; correct?
A. That is correct.
Q. All right. And we're going to talk about these RCTs. I'll put "not on Gore-Tex used by Dr. R."
A. Correct. But, sir, when I was using Gore-Tex, it was under an experimental protocol. So, patients knew that we were testing this product out, and we ultimately wrote a paper about it.
Q. All right. And the TVT-O that you used and, during the period of time from '04 to '07 that we've talked about, do you recall that?
A. Yes.
Q. You were aware of the fact that there were no randomized

clinical trials done on that product prior to the time that it was put out on the market; correct?
A. That is correct.
Q. And you knew that from your own personal experience because you keep up on products; correct?
A. Well, I had met with the inventor of the TVT Obturator and we discussed his experience and literature that he published on it.
Q. All right. But the fact that there was no RCT on the TVT-O did not prevent you from relying upon your own clinical experience and then implanting it in 40 to 50 women; correct?
A. That is correct.
Q. And when you were talking with the inventor about that and he told you that -- well, let's talk about that. When did the inventor tell you there was no RCT on the TVT-O?
A. Well, there was -- when the TVT Obturator was launched, there were, there was a cohort study of, if I remember correctly, 120, 130 patients.
Q. All right. After the launch; correct?
A. That was around the time of the launch.
Q. All right. And let's talk about shrinkage and contracture briefly. You had mentioned that there is an article concerning -- and the name of the article was Wang, I think, A.C. Wang that you referenced?
A. That is correct.

Q. And are you aware of the studies that have been done by Dr. Dietz on the issue of shrinkage of polypropylene mesh that is used in the female pelvis?
A. Well, actually the study by Wang is on degradation.
Q. Okay. Well, let's talk about shrinkage and contracture. Are you aware of the studies done by Dietz on the issue of whether polypropylene mesh shrinks or contracts inside the female pelvis?
A. That is correct.
Q. All right. So, you are aware of that?
A. Yes.
Q. And you're aware that Dr. Dietz in an article in 2003 entitled "Does Tension-Free Vaginal Tape Stay Put --" let me strike that. Dr. Dietz in an article dated 2003 entitled "Does the Tension-Free Vaginal Tape Stay Where it is Put" concluded that there is no evidence of shrinkage or mesh contracture; correct?
A. That was his conclusion which goes against a very large body of literature that shows that another gentleman, Dr. Letouzey, followed up mesh for eight years and found --
Q. Mr. Monsour can ask you about Letouzey.
MR. MONSOUR: Objection.
THE COURT: That objection is sustained. I want him to be able to give a complete answer as I've previously ruled.
Finish your answer, please.

THE WITNESS: Dr. Letouzey's study showed that after eight years, there was 85 percent mesh contracture, and that this continued from year one all the way up to year eight.

BY MR. ADAMS:

Q. Okay. And the Dietz article that we were talking about, I'm not going to take the jury's time to go through that, but you will recognize that that article was published in a scientific journal; correct?

A. That is correct.

Q. And not only did Dietz, did Dietz publish that article in 2003, but then he later published an article in the *American Journal of Obstetrics and Gynecology*. That's the green journal; correct?

A. That's the gray journal.

THE COURT: Is there an objection, counsel?

MR. MONSOUR: Yes. Can he be provided -- he's being asked pretty extensive questions. Can he be provided a copy of that study as can I?

MR. ADAMS: I will.

BY MR. ADAMS:

Q. Let me ask you if you're familiar with the study first. Are you familiar with Dr. Dietz's later article that appeared in the gray journal in February of 2011?

A. That is correct.

Q. Okay. Well, --

THE COURT: Provide the copy then, please, counsel.

MR. ADAMS: Certainly.

BY MR. ADAMS:

Q. Here's Exhibit 1306. And I've got a copy for Mr. Monsour. Briefly, this article is on the issue of mesh contraction; correct?

A. That is correct.

Q. It says "Mesh Contraction, Myth or Reality." Correct?

A. That is correct.

Q. And what he did is he examined mesh and did a study on it on over -- I'm sorry. There were 40 women assigned to the study; correct?

A. That is correct.

Q. And, "Over an observational period of almost 60-woman years, we found no evidence of mesh contraction." Correct?

A. That is based on ultrasound, yes.

Q. And, so, you'll agree with me that Dr. Dietz, as published in this scientific article that was peer-reviewed, concluded that he didn't observe mesh contraction or shrinkage in almost 60-woman years; correct?

A. That is correct.

Q. These -- I'd refer to the AUGS statement. And you know from reviewing my opening statement that I talked about that and we had -- the jury's already heard about that; correct?

A. That is correct.

Q. But you're aware of the fact that not only AUGS but several other major groups of physicians who practice in the area of urology and urogynecology have issued the same or similar statements; correct?
A. Including the European Association of Urology and the American Urologic Association.
Q. Very good. And you're right. So, the AUA, the IUGH, and the European society; correct?
A. European Association of Urology, yes.
Q. Okay. Now, with respect to the Cholhan study, we've already talked about the Cholhan study a little bit. And Cholhan was an article and we've established that there were -- by the way, Mr. Monsour referred to Cholhan as a Boston Scientific study. Do you recall that?
A. That is correct.
Q. And you're aware that that study was actually performed by outside researchers who are practicing physicians in Canada; correct?
A. That is correct.
Q. And, so, it wasn't Boston Scientific people that were actually doing the study; correct?
A. No. It was funded by Boston Scientific.
Q. Right. And on the article it says it's funded by a grant from Boston Scientific; right?
A. That is correct.

Q. And you're aware that in the -- it's common for studies on medical devices for companies to actually issue a grant to independent doctors who can do their own research; correct?
A. That is correct.
Q. And one of the reasons that companies do that is that if -- well, when they give that money to independent doctors, it's to fund the research. But Boston Scientific doesn't have any control over the research; correct?
A. We would hope so.
Q. Right. Then that's the way the grant process works; correct?
A. We would hope so.
Q. Okay. And you're not aware of any kind of monkey business going on with respect to the Cholhan or any of the other studies funded by Boston Scientific; correct?
A. Not that I'm aware of.
Q. All right. And Cholhan involved 25 Obtryx devices; correct?
A. That is correct.
Q. And Mr. Monsour brought out that, well, there was a 24 percent rate of dyspareunia. Do you recall that?
A. Yes.
Q. And, so, out of the 25 women who were studied, there was a 24 percent rate of dyspareunia. But how many women did that actually account? How many exact numbers?

A. A quarter of 25 would be around six.
Q. Well, actually the article says much lower. Do you have it up there? Not much lower, but I think it was four.
A. It was four out of 17 because that was the number of patients that were still having -- that were having intercourse at the time. If you're not having intercourse, it's difficult to have pain with intercourse.
Q. Okay. So, the number was actually four; correct?
A. Out of 17, yes.
Q. All right. And I'll put "24 paren 17." Correct?
A. No, that's the -- it was four out of 17.
Q. You're right. And I should have done this. I'll put "4 over 17." Fair?
A. That's fair.
Q. Okay. And, now, those doctors in Canada that are listed on the Cholhan report, would it surprise you to learn that those doctors actually still use and implant --
MR. MONSOUR: Objection. Your Honor, there's no foundation for this. Are they going to testify?
THE COURT: You didn't get your question out totally. I think that I know what the question is, counsel. I will let you respond to the objection if you want.
MR. ADAMS: I do. Well, I better approach. I don't want to say something that --
THE COURT: All right.

(The following occurred at sidebar.)

MR. ADAMS: These doctors continue to use the Obtryx device. That's what -- I'm going to ask him whether he's aware of the fact that the doctors in the Cholhan study continue to use the Obtryx device.

MR. MONSOUR: It's an improper question. He knows the answer. He's just throwing it out there. He's going to throw a skunk in the jury box and I can't get the smell out.

MR. ADAMS: I have a good faith basis for asking the question.

MR. MONSOUR: But he has no evidence to support that basis.

MR. ADAMS: I have a woman from Boston Scientific who was involved with the study who knows that they still use it.

THE COURT: Then we should call her as a witness so she can be subject to cross-examination, Mr. Adams. When we are -- well, I'm going to sustain the objection --

MR. ADAMS: Fair enough.

THE COURT: -- to the leading question regarding their continued use. I have no reason to believe that this expert used it in any way. And, therefore, I find that it is getting evidence in before the jury without an opportunity for the plaintiff to cross-examine.

MR. ADAMS: Fair enough.

THE COURT: I preserve the defendant's objection and

exception.

MR. ADAMS: And I did want you to know that the reason why I approached is I didn't want to say that in front of the jury until you ruled on it.

THE COURT: That's fine. I appreciate that.

MR. ADAMS: Okay.

(Sidebar concluded.)

BY MR. ADAMS:

Q. All right. We were talking briefly about Cholhan. And I misspoke, Doctor. I need to clarify that. The Cholhan actually involved doctors located in New York. Do you recall that?

A. Yes. The Ross study was actually in Concord.

Q. You're right, and I mixed that up. Ross is in Canada. Cholhan was in New York. Correct?

A. That is correct.

Q. And, now, you have talked about Cholhan -- that Cholhan talked about the issue about banding; correct?

A. That is correct.

Q. And you have seen the issue of banding occur in other mid-urethral slings; correct?

A. That is correct.

Q. And you'll agree with me that 89 percent of the Obtryx group in the Cholhan study did not experience any type of deterioration in their post-operative sexual function;

correct?
A. Of the ones that were having intercourse, 75 percent did not have dyspareunia.
Q. Okay. And the article also talks about -- when it discusses the complications, it says most of these complications are transient and reversible and, thus, do not have significant long-term repercussions; correct?
A. And where are you looking at?
Q. That's in the Cholhan study.
A. What page?
Q. It is on -- bear with me, Doctor. It's on another copy.
A. Because we need to know what kind of complications he's talking about. If he's talking about the patient had some immediate post-operative pain, that would be different from someone that has life-changing dyspareunia.
Q. I'm sorry, Doctor. I found it. I had the wrong copy. This is on the last page underneath "Conclusions." And this is in the right-hand column up towards the top. Do you see that?
A. Yes.
Q. And it says, "Increased implementation of TO slings has yielded increasing reports of complications. Most of these complications are transient and reversible and, thus, do not have significant long-term repercussions."
Did I read that correctly?

A. That is correct.
Q. All right. And with respect to the Ross study, now, the Ross study -- the conclusion of the Ross study was that the authors would recommend the use of the Advantage over the Obtryx; correct?
A. That is correct.
Q. And the Ross study was done in 2009; correct?
A. It would be helpful if I had a copy of it so that I could follow along with you.
Q. Certainly. Let me give you one. And this is Defendant's Exhibit 1505.
A. Thank you, sir.
Q. And that's the same study that we talked about with Mr. Monsour; correct?
A. That is correct.
Q. And this study was done in 2009; correct?
A. It was published in 2009.
Q. Right. And it was described as level one evidence; correct?
A. That is correct.
Q. Because it's an RCT; correct?
A. A randomized controlled trial, yes.
Q. And there has been another RCT done on the Obtryx that is very recent; correct?
A. That is correct.

Q. All right. And at the time of your deposition, isn't it true that you had researched the articles available on the Obtryx and the only two articles that you found were Ross and Cholhan; correct?

A. No, I had several others, the Smith article and a few of the abstracts.

Q. Okay.

A. Sometimes it's more difficult to get abstracts. They're not published in the peer-reviewed journal. They're just somebody that's presented at a meeting so that people can get feedback on the research. So, it hasn't gone through a peer-review process to be presented as an abstract.

Q. Now -- and -- but in your material that you reviewed and you relied upon for your opinions in this case, the only two articles on the Obtryx were Cholhan and Ross; correct?

A. In the Rule 26 report, yes.

Q. Right. And in the Rule 26 report you must list all the studies or documents that you have reviewed or are relying upon; correct?

A. For the opinions, yes.

Q. All right. And, so, you didn't review -- well, strike that. You didn't list for your opinions documents that you may have considered that reach opposite conclusions or different conclusions than Ross and Cholhan on the Obtryx; correct?

A. Those were the two that I used in my report, yes.
Q. Right. But you did not list on your report any of the other studies done on the Obtryx; correct?
A. At that time, those were the two that were in peer-reviewed literature.
Q. Okay. And on the Ross study, if we could pull that up just briefly. And this is 1505.
MR. ADAMS: And, Your Honor, may I publish it? I believe Mr. Monsour already established this is a learned treatise and cross-examined him on it.
THE COURT: Yes, sir.
MR. ADAMS: I'm sorry, did a direct exam with him on it.
THE COURT: Yes, sir.
MR. ADAMS: Thank you, Your Honor.
BY MR. ADAMS:
Q. If you would put up 1505 and if we could real quickly go to this article. The jury's already seen this. And if we will turn on Page 1291, Jim, just briefly and blow up the highlighted section.
Now, part of this article was the doctors making observations about the existence of palpable mesh; correct?
A. That is correct.
Q. And what palpable mesh means is that when you push on an area, you can feel it; correct?

A. That is correct.
Q. And, so, for like a hernia surgery, you can push on an area for somebody that's had hernia surgery using mesh and you can actually feel that there is something there to bolster the tissue; correct?
A. That is correct. And, in fact, there's a, a medical condition called pain in the inguinal area from inguinal mesh.
Q. Right. And you'll agree with me that not everybody that gets a hernia operation with mesh experiences any type of problem; correct?
A. Actually, the amount of patients that have hernia surgery that have problems is, is not insignificant.
Q. Okay. Now, in this article one of the things that they reported was actually the interviews and the expectation of the women who went under the procedure of either having an Obtryx used or an Advantage used; correct?
A. That is correct.
Q. And it says in this column, right before the discussion it says, "The majority of women reported that the surgery met their expectations (78) --" and 78 is the number of women actually; correct?
A. That is correct.
Q. And the percentage of women in the Obtryx group was 90.7 percent; correct?
A. Well, that was the number of women that completed the

one-year evaluation. So, these --

Q. Fair enough.

A. This is the information that they're obtaining at the end of one year.

Q. Fair enough. And when you were talking with Mr. Monsour, you were relying upon the same one-year information; correct?

A. That is correct.

Q. Right. And at one year 90.7 percent of the women in the Obtryx transobturator group said that the surgery met their expectations; correct?

A. That is correct.

Q. And as compared with 84 percent in the TVT group; correct?

A. That is correct.

Q. And it said they would recommend the surgery to someone else with similar symptoms. 95 percent of the ladies in the Obtryx group said they'd recommend it to somebody else compared with 88 percent or, I'm sorry, 92 percent in the TVT or the Advantage group; correct?

A. That's what the paper states, yes.

Q. Right. So, what the paper states is that according to the actual women who were involved in the study, those women prefer the results of the Obtryx over the results of the TVT; correct?

A. At one year, yes.

Q. Doctor, I've got one last study to discuss with you. Actually, I lied. Two last studies and I'll be quick about it. The most recent study that was done on the Obtryx, have you read that prior to coming in here to testify?
A. That is correct.
Q. All right. And that is the Tarcan study; correct?
A. That is correct.
Q. And Tarcan, like the Ross study, is a randomized clinical trial; correct?
A. That is correct.
Q. And the Tarcan study was published just recently in 2014; correct?
A. That is correct.
Q. The Ross study we've established was published in December of 2009; correct?
A. That is correct.
Q. And, so, now almost five years later we have another RCT from Tarcan; correct?
A. That is correct.
Q. And the Tarcan study was published in the *International Urology Journal* and it's, it's designated as *Urology International*. You're familiar with that journal; correct?
A. Actually, that is a rather obscure urology journal from Italy if I'm correct.
Q. Let me hand this to you and I'll give you a better copy.

MR. ADAMS: And I've got a copy for you, Mr. Monsour, a copy of Defendant's Exhibit 1158.

MR. MONSOUR: I've got it.

MR. ADAMS: Okay.

BY MR. ADAMS:

Q. And this journal, you're aware of the fact that this is a peer-reviewed journal; correct?

A. Again, this is an obscure journal, so I will take your word that it is a peer-reviewed journal.

Q. All right. And you recognize papers like this from a peer-reviewed journal as being authoritative, correct, or at least reliable; correct?

MR. MONSOUR: Objection.

THE COURT: The objection is overruled. I'm going to let him answer if he can.

THE WITNESS: I don't know this journal in particular. There are good peer-reviewed journals. There are journals that pretty much accept any article that comes along. So, it's difficult to say. This is not one of the top urology, urogynecology, or OB/GYN journals.

Q. Okay. And --

THE COURT: Let me interrupt, Mr. Adams.

Mr. Monsour, I should have let you state your grounds for your objection. Did I understand it?

MR. MONSOUR: I withdraw my objection. He can

proceed.

THE COURT: All right. Thank you. Go ahead, please.

BY MR. ADAMS:

Q. And, sir, before you testified today did you at least review this article?

A. Yes, sir.

Q. And, so, you've reviewed it in connection with the opinions that you were giving in this case; correct?

A. That is correct.

Q. And because you wanted to consider all evidence concerning testing or randomized clinical trials done on the Obtryx; correct?

A. That is correct.

Q. That was part of your work as an expert; correct?

A. That is correct.

MR. ADAMS: And, Your Honor, on that basis, I move to publish the article because he's reviewed and studied the article as part of his work as an expert.

THE COURT: Any objection, counsel?

MR. MONSOUR: A limiting objection that Mr. Adams follow any prior motions *in limine* made by either you or Judge Goodwin. I think he knows what they are.

THE COURT: I expect both, all parties at all times to follow the prior rulings of the Court, counsel.

MR. ADAMS: I do too and I addressed his concern.

THE COURT: All right. Go ahead.

MR. ADAMS: Frankly, I didn't know where he was going, but now I do and I appreciate counsel's statement.

BY MR. ADAMS:

Q. Let's talk about this article really quick.

MR. ADAMS: Your Honor, may I put it up on the screen now?

THE COURT: Yes, sir.

BY MR. ADAMS:

Q. It's 1158. Now, this article -- and I realize that you're not familiar with the journal. But it's called "Safety and Effective --" "Safety and Efficacy of Retropubic or Transobturator Mid-Urethral Slings in a Randomized Cohort of Turkish Women." Correct?

A. That is correct.

Q. And this is a study that was published on April 24 of 2014; correct?

A. No. That's when it was received by the journal. Then approximately one month later they received the revisions, and then it was published online August 20th, 2014.

Q. That's my point. So, it was received on the 24th and then published more recently in August; correct?

A. That is correct.

Q. And this article, it says at the top in this paragraph that -- underneath "Objective" it says the aim of this study

was to evaluate -- let me slow down. It says, "The aim of this study was to evaluate the safety and efficacy of retropubic or transobturator TO mid-urethral slings in a prospective randomized cohort of Turkish women."

Now, the RCT we've established is level one evidence; correct?

A. The RCT can be level one evidence. It not only has to be randomized and controlled but, as I talked about before, it has to have a large sample size and it has to have reliable methodology which you'll find in the methodology section.

Q. Okay. And this -- it goes on to say that a total of 54 women with urodynamic stress urinary incontinence were randomized to undergo either retropubic or transobturator MUS, mid-urethral slings, between August, 2006, and February, 2013, in a tertiary referral center by a single surgeon. Correct?

A. That is correct.

Q. And I don't think the jury's heard that term "tertiary referral center." What's that mean?

A. Well, they actually go on to explain that at the end of the article. They say that they are a referral center for -- the reason why it took them seven years to collect 50 patients, that's about eight patients a year, was because they get referrals from other doctors.

And mostly what they get, as they state on Page 4, is they say that they might have a low number of patients that

are referred to them because they're mostly dealing with complications.

So, this is an article about slings. Probably what they're dealing with is mid-urethral sling complications.

Q. All right. And it says, "All patients --" we've already read that. Let's go down to the bottom part on the results and real quickly read this, if we could blow up the next portion that's highlighted.

It says, "The Advantage retropubic and the Obtryx transobturator mid-urethral sling systems were used for all RP and TO procedures."

Did I read that correctly?

A. That is correct.

Q. And it then says, "27 patients were randomized to each group."

Did I read that correctly?

A. Yes, you did.

Q. And then it says, "The overall objective and subjective cure rates were between 92.6 and 79 percent respectively. The quality of life of all patients significantly increased after the operation compared to their pre-operative," and the next word is "status."

Did I read that correctly?

A. That is correct.

Q. And then under "Conclusion" it says, "Mid-urethral sling

surgery is highly effective and could safely be performed in a cohort of Turkish women with stress urinary incontinence in subspecialty centers by experienced surgeons. There is no significant difference between retropubic or transobturator --" and the transobturator is the Obtryx; right?

A. In these 50 patients, yes.

Q. "There is no difference between the RP or the TO applications in terms of safety and efficacy."

Did I read that correctly?

A. That is correct.

Q. And you know, sir, that the Obtryx continues to be used by doctors throughout the world; correct?

A. Not in Scotland.

Q. All right. All the other countries doctors continue to use the Obtryx; correct?

A. Australia is actually looking at the, the issue too.

Q. Not my question. The Obtryx is being used in those, all those other areas of the world besides Scotland; correct?

A. I don't know of other countries that have prohibited the use.

Q. Now, --

THE COURT: Mr. Adams, I want to give the jury a break. I thought I would get to a stopping point.

MR. ADAMS: I'm very close.

THE COURT: They've been in the box for two hours.

MR. ADAMS: And let's take a break, Your Honor, and I'll organize my thoughts and I'll finish quickly.

THE COURT: Ladies and gentlemen of the jury, I'll give you a recess. While you're out, do not discuss the case among yourselves or permit anyone to discuss it with you or in your presence. And please be in your jury lounge at five minutes till the hour.

(A recess was taken from 3:33 p.m. to 3:55 p.m.)

(The Jury entered the courtroom at 3:55 p.m.)

THE COURT: Mr. Adams?

MR. ADAMS: Thank you, Your Honor. May it please the Court.

THE COURT: Yes, sir.

BY MR. ADAMS:

Q. Dr. Rosenzweig, I've just got a couple of more points, and then I'll turn it over to Mr. Monsour.

This second retropubic sling that was placed on March 18th of 2013, it has resolved any complaints that Ms. Blankenship has as a result of stress urinary incontinence, correct?

A. That is my understanding, yes.

Q. And her current complaints consist of chronic pain and dyspareunia, correct?

A. That is correct.

Q. And with respect to Dr. Lassere, we talked about him. I wanted to clarify that you know that Dr. Lassere, after using the product, the Obtryx product, he did start using another product as a result of a change in the hospital, correct?
A. That's what he testified to.
Q. Right. And he agreed that he didn't switch for any reasons of safety or efficacy, correct?
A. That's what he testified to.
Q. Okay. And then the last issue, on the day when Dr. Lassere examined Ms. Blankenship, prior to doing the procedure, he took a history, correct?
A. That is correct.
Q. And this is part of Exhibit 14, which is already in evidence.

MR. ADAMS: And, Your Honor, may I display this?

THE COURT: Yes, sir.

MR. ADAMS: Okay.

(The document was published to the jury.)

BY MR. ADAMS:
Q. So pre-procedure, Dr. Lassere, in this record, had examined Ms. Blankenship.

MR. ADAMS: And blow it up a little bit higher than that, Jen.

BY MR. ADAMS:
Q. To clarify, he says, "Patient has also significant

problems with urinary incontinence. She has been wearing adult diapers for the past two years for protection," correct?

A. That is correct.

Q. You and I talked about that earlier, correct?

A. That is correct.

Q. And, again -- and this is the day that he does the procedure, correct?

A. That is correct.

Q. And he obviously -- on that day, he also notes that her prior history is that "Patient does have other symptoms of pelvic discomfort, pain with sex, and pain with her menses, which may warrant workup in the future." Did I read that correctly?

A. That is correct. And --

Q. That exists before the Obtryx, correct?

A. That is correct. And she gave that on the day that she had a urinary tract infection.

Q. And then when we look at -- under "plan" on the last page, it says -- if you can blow that up -- it says, "Will consider expectant management of her chronic pelvic pain problems and work up as needed." Did I read that correctly?

A. That is correct. Expectant management means doing nothing.

Q. Okay. And I don't have any other questions for you at this time, and I appreciate your patience, Doctor.

THE COURT: Redirect, Mr. Monsour.

MR. MONSOUR: Thank you, Your Honor.

(REDIRECT EXAMINATION OF BRUCE ROSENZWEIG BY MR. MONSOUR:)

Q. Are you ready?

A. Yes, sir.

Q. Okay. There was a lot of things that were discussed with Mr. Adams, so I'm going to -- I want to be organized, but I'll try and address them one by one if I can.

The first thing I want to do is I want to talk to you about the last study that was put in front of you, which was the Tarcan study. And the Tarcan study was the Turkish study, and you were shown this by Mr. Adams, and it said, in the Obtryx group, there was a 79 percent success rate. Do you remember that?

A. That is correct.

(The document was published to the jury.)

BY MR. MONSOUR:

Q. Now, if you look -- if I look at the front part of the document, it talks about how there was follow-up at 48 months, but if we look -- oh, okay. If you got -- if you will look here on the first page, it talks about a success rate -- and if you can blow that up -- the success rate for the TOT procedure, which was the Obtryx, was 79 percent, correct?

A. That is correct.

Q. Is that an impressive success rate in your opinion?

A. No, because that data point was collected at one year.
Q. Okay.
A. Success rate at one year was 79 percent.
Q. Okay. But when you say you have a success rate of 79 percent, that means at one year, 21 percent of the procedures failed. That's one in five, correct?
A. That means that they are still leaking urine when they cough and sneeze, that is correct.
Q. At one year, correct?
A. That is correct.
Q. How does your Burch procedure stack up to these results found in an obscure Turkish journal?
A. It's 90 to 95 percent successful at one year.
Q. Okay. Now, let's turn to the second page of the obscure Turkish journal, and if we can look at --

MR. ADAMS: Objection, Your Honor. I object to the mischaracterization.

THE COURT: The term "obscure"?

MR. ADAMS: Yeah.

THE COURT: I am going to sustain the objection. Based on the testimony of the witness, the jury can determine what weight to give to it. I don't think you lawyers should add weight to it in the questions.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. Under the "results" section, if we look above, it talks about in the third paragraph, in that paragraph, yes, it says, "Subjective and objective cure rates were evaluated at months 1 and 12 after surgery." Is that correct?

A. That is correct.

Q. Okay. So let's go back to Jeanie Blankenship. If data was collected at one year, the problems that Jeanie Blankenship has would not show up in this Turkish study, correct?

A. That is correct.

Q. Okay. Now, at the back of the Turkish study, it says, on the last paragraph before conclusions of the Turkish study, it says, "The major limitation of this study is related to the relatively low number of patients recruited over a wide range of time." Do you remember that?

A. That is correct.

Q. Then it says, "Another" -- down at the bottom, "Another obvious limitation is that our results can only be validated in a short-term follow-up." That's the 12-month data collection point, correct?

A. That is correct.

Q. Okay. It says, "Also, this study is unable to provide data on the effect of stress urinary incontinence surgery on sexual function or standardized classification of the complications." Correct?

A. That is correct. This is not a safety study.
Q. Okay. So, and if we go up into the previous paragraph immediately above that, right there, do the bottom half down, if you can.
This is the one I want you to focus on. I want you to explain to the jury why this is important. It says, "Since not all synthetic devices are equal, only those meshes that have been tested in carefully controlled clinical trials with adequate safety, efficacy and adverse event data should be used." Is that what it says?
A. That's what it says, and that's what I agree with.
Q. Okay.
A. That we need data to say whether something is safe and effective. These are devices that are going to be implanted in a woman's body for 35 years. We need to know that it's safe and effective longer than one year to be able to draw any conclusions.
Q. Okay. Now, if we look at this study, is this study actually saying use this study to show how safe the product is, or what is this study saying?
A. Well, this study, first of all, said that it wasn't able to monitor complications such as pain with intercourse or other complications; secondly, they admitted that it is a short-term study; and, third, they go on to say that in order to be able to say whether something is safe and effective, you

need a longer term study.
Q. So they say we need longer term studies that collect safety data, and, by the way, we're not a long-term study and we don't collect safety data; fair enough?
A. That is correct.
Q. All right. I want to talk with you about the Dietz paper. Now, the Dietz paper sounds impressive. It's a 60-year study that shows no shrinkage. So, by my chart, it says, one, two, three, four, five, six, seven, eight, nine, ten, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 -- let's keep going. That study should come out to probably somewhere around here. That's a pretty long-term study. That's 60 years. That is powerful, Doctor. How can you refute the Dietz study that is so powerful, it's 60 years long?
A. Well, what they say is, women years. So what they do is they multiply the number of women by the number of years that they were following them to get 60 women years.
Q. So let me see if I understand this. On the ELMO, it says -- on the ELMO of the Dietz study, it says, "In conclusion, we have not observed any evidence of mesh shrinkage in 40 women after Perigee mesh implantation followed up for an average of 18 months." Is that what it says?
A. That's what it says.
Q. So, again, we could stack up 40 different Jeanie Blankenships, and we never even make it to the 21-point

symptom mark.

MR. ADAMS: Objection, Your Honor, leading.

THE COURT: The objection is sustained, inasmuch as there was no question there, period, not even in tone, Mr. Monsour.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. Was the last statement that I made correct?

A. That was correct.

THE COURT: Well, that is asking him to affirm your testimony and I have not put you under oath, so I won't permit that either, counsel.

MR. MONSOUR: All right. I will restate my question, Your Honor.

THE COURT: All right.

BY MR. MONSOUR:

Q. In the Dietz study, the average woman that was looked at was 18 months; is that fair?

A. That is correct.

Q. And with regard to the -- looking at 18 months, when did Jeanie Blankenship's symptoms first show up?

A. Approximately 21 months.

Q. So if we had looked at Ms. Blankenship or we were looking at this from a symptoms basis, we probably -- or we might not have even seen that with Jeanie Blankenship, who does have

problems. Is that fair?
A. That is correct.
Q. Okay. Now, you were asked about your use of other synthetic meshes, do you remember that, by Mr. Adams?
A. Yes, sir.
Q. And they asked you -- or he asked you about your use of TVT, and your use of TVT-O. Is that correct?
A. Yes.
Q. Now, before -- and he asked you, he said, before J&J marketed those products; did they do a randomized controlled trial on them? Do you remember that question?
A. Yes.
Q. And your answer to that question was what?
A. No.
Q. Let me ask it another way. Did J&J, the competitor of Boston Scientific, look at this product or these products in women's vaginas and test them in women's vaginas before they sold the products?
A. Yes.
Q. For the TVT product, how many women were implanted with a synthetic mesh device before marketing?
A. Well, there was a study done by the company that sold the device to Johnson & Johnson called Med Scan, and they had 131 patients. Prior to that, the inventor had done a study on a device that he made himself which was with the prototype and

had somewhere around 60 or 70 patients, if I remember correctly.

Q. Okay. All right. With regard to their follow-up product which would have been, like, the first was the TVT, the retropubic. (Indicating.) The second product was the TVT-O, the obturator product. (Indicating.) Did they then later test that product on women before they marketed it? And when I say test it, I mean implant it, transvaginally, as it would be intended after marketing.

A. That is correct.

Q. And how many women did they look at?

A. There was a study by Dr. de Leval that had approximately 120 to 130 patients.

Q. So if we look at the lowest numbers, we take about 180 on the low end, what is that? 311? On the low end, 311 women were looked at by J&J with these products implanted before marketing, correct?

A. Actually, the number is higher. I forgot to mention that there was a study by Dr. Wang that was also accomplished, and I can't remember the number, but it was somewhere around a hundred patients.

Q. Okay. So I'll say -- (Indicating.)

Now, we heard yesterday during the testimony of Peggy Pence that Boston Scientific looked at 36 rabbits, and that for the second product, they used the same data from the same

36 rabbits.

Can you think of any reason why a company that would be implanting a product in a woman's vagina would perform this step but would not perform the second step before they marketed the product? (Indicating.)

A. I could speculate that it might be cheaper to do it in rabbits.

Q. Okay.

MR. ADAMS: Move to strike the speculation, Your Honor.

THE COURT: The objection to the answer as to speculating as to it being cheaper, that objection is sustained. Ladies and gentlemen, I'm going to order it stricken from the record and that it not be a part of your consideration in this case.

BY MR. MONSOUR:

Q. Now, you mentioned before your testifying experience. You were cross-examined about that, correct?

A. That is correct.

Q. Do -- of the money that you have been paid in -- for being an expert in transvaginal mesh, has that involved a significant number of women?

A. Yes.

Q. Give us a ballpark of how many.

MR. ADAMS: Objection, Your Honor. May we approach?

THE COURT: Yes, sir.

(The following occurred at sidebar.)

MR. ADAMS: This is a back-door way of getting in the number of lawsuits, which I don't think he's entitled to get in.

MR. MONSOUR: He brought it up, so it sounds like he's made a million dollars working on this case and that's very misleading. I mean, half these people were patients of Bard or J&J. There is a lot of case-specific work with -- his work on Boston Scientific has been relatively minimal. If he's going to cross-examine him about J&J and Bard, I've got to clarify it.

MR. ADAMS: He's testified --

THE COURT: I'm going to preclude any evidence that gets into other lawsuits consistent with the prior rulings.

I believe that portion of his testimony, Mr. Monsour, where he was asked about that litigation with respect to Boston Scientific is not such that the jury necessarily would infer that it is this case. And, again, I do not think that that opens up the door to getting into the other lawsuits and I'm going to preclude it, preserving the plaintiffs' objection and exception.

MR. MONSOUR: Can I tell you my next question and ask if it's okay since it might cross the line and I don't want to do that?

THE COURT: Okay.

MR. MONSOUR: This case involved more plaintiffs beforehand and on one of the plaintiffs, we sent her medical records to them and he said this is not a case and he told us to drop the case. Can I ask that question?

THE COURT: I think because his credibility and his bias is always an issue, you can ask him whether he has ever refused a plaintiff's case if you want to.

MR. MONSOUR: Okay, okay. Thank you.

THE COURT: If you want to object to that, I will permit you to and preserve it.

MR. ADAMS: I do object to it. I mean -- well, if you can stay away from this case.

MR. MONSOUR: I will. I will just say generally, not this specific case --

THE COURT: I believe that's fair because in cross-examination, there were some questions asked that established bias if the jury decides to interpret it in that way, and so I believe that this is appropriate redirect in the manner that I have instructed it to be asked.

MR. MONSOUR: Okay. Thank you.

MR. ADAMS: And note my objection and I appreciate the Court's ruling.

THE COURT: I preserve the defendant's objection and exception.

MR. ADAMS: Thank you.

(Sidebar concluded.)

BY MR. MONSOUR:

Q. Without naming the case or giving any -- anything too specific, have we asked you to look at cases before involving plaintiffs with transvaginal mesh where you've said, Doug, there's not a case here?

MR. ADAMS: Objection, Your Honor. I don't -- well --

THE COURT: You don't?

MR. ADAMS: Well, my statement is, I don't believe that that was consistent with what the Court said at the bench.

THE COURT: I sustain that objection.

MR. ADAMS: Yes.

MR. MONSOUR: Let me reask the question.

(Discussion held off the record between Mr. Adams and Mr. Monsour.)

THE COURT: I'm feeling very left out up here.

(Laughter.)

MR. ADAMS: Your Honor, I was trying to assist him.

THE COURT: All right. Go ahead, Mr. Monsour.

BY MR. MONSOUR:

Q. Let me try again.

Is it a fair statement to say that you have refused to

testify on behalf of a plaintiff before?
A. That is correct.
Q. In other words, every case that is sent to you, you don't agree to be an expert on?
A. That is correct.
Q. Okay. Now, you were also asked about your testimony in medical malpractice cases. Do you remember that?
A. Yes, sir.
Q. Is there anything wrong with representing patients?
A. No.
Q. Do you have any second thoughts about being willing to testify when people are injured?
A. No.
Q. Do you stay up late at night worried that some of your brethren might get their feelings hurt if you criticize them when they make a mistake?
A. I think that that is a concern.
Q. But you do it anyway.
A. Yes, sir.
Q. Now, in these cases, you were looking at the medical -- you looked at the medical record in Ms. Blankenship's case, correct?
A. That is correct.
Q. If you had seen medical error by Dr. Lassere, you would have told me, right?

A. That is correct.
Q. You didn't, you didn't mention anything, did you?
A. That is correct.
Q. And that's because you could rule it out by the delayed reaction of the sling slowly shrinking over time, right?
A. That is correct.
Q. If a sling is implanted properly, with the proper tension, and over time it shrinks up, that's not the doctor's fault, is it?
A. No.
Q. Would it be inappropriate for Boston Scientific to blame Dr. Lassere for the problems of Ms. Blankenship?
MR. ADAMS: Objection. One, cumulative. Two, we have already established we're not blaming him.
THE COURT: I understand the latter part of your objection. Counsel, I'm going to overrule it and permit the question.
MR. MONSOUR: Thank you.
BY MR. MONSOUR:
Q. Would you answer the question?
A. That would be inappropriate.
Q. Now, you were asked questions about the directions for use and what Dr. Lassere went over with Ms. Blankenship. Do you remember those questions from Mr. Adams?
A. Yes.

Q. And he asked you, he said, isn't it true that you read from Dr. Lassere's deposition that he went through all the problems with her that are listed in the directions for use; do you remember that?
A. Yes.
Q. If Dr. Lassere went through all of the problems that are listed in the directions for use and only those problems, would he have gone through lifelong complications?
A. No.
Q. Would he have gone through shrinkage?
A. No.
Q. Would he have gone through contraction?
A. No.
Q. Would he have gone through degradation?
A. No.
Q. Would he have gone through the fact that the product cannot be removed?
A. There is no standardized, reliable, effective way of removing all the mesh in women that have had obturator slings, if it creates a problem.
Q. Let's look at the directions for use and let's see what he would have gone through with her.
(The document was published to the jury.)
MR. MONSOUR: If we can zoom in.
BY MR. MONSOUR:

Q. It notes here, "Tissue responses of the implant could include vaginal extrusion, erosion through the urethra, or other surrounding tissue, migration of the device from the desired location, fistula formation, and inflammation. The occurrence of these responses may require removal of the entire mesh." Did I read that correctly?

A. Yes, you did.

Q. It seems simple enough. If you've got a problem, just take it out. We put it in in 20 minutes. We'll just take it out. Easy enough, right?

A. Actually, no.

Q. So when Jeanie Blankenship is meeting with her doctor, he's telling her, hey, if you got one of these problems, we'll just take it all out, right?

MR. ADAMS: Objection, Your Honor. This is all leading and counsel's testifying.

THE COURT: Counsel, with respect to that question, I am going to sustain the objection. I told you all before, I think it's proper with respect to certain issues to lead an expert. This is not one of those questions.

MR. MONSOUR: I will rephrase.

THE COURT: All right. I sustain the objection.

MR. MONSOUR: Thank you, Your Honor.

BY MR. MONSOUR:

Q. If Dr. Lassere went through the directions for use, would

he have told her that the mesh could be removed in its entirety?

A. Well, that's what's suggested by the instructions for use.

Q. Okay. And is there anything in here that talks about the difficulty in removing the mesh?

A. No.

Q. Let's talk about balancing. So when Jeanie and Dr. Lassere are sitting down and Jeanie's making the decision, let's talk about what can go wrong with me, how is she supposed to make a good decision when she doesn't know about all these problems?

A. That would be quite difficult.

Q. Now, another thing I want to ask you about is the editorial, the AUGS editorial. I think Mr. Adams likes it, so I want to ask you a question about it.

The AUGS editorial, it talks about 99 percent of the doctors that use slings. You started an answer, you didn't get a chance to finish it. Would you tell the ladies and gentlemen of the jury why is the AUGS statement, in your opinion, unreliable?

A. Well, that statement is based on a study that was published by a Dr. Clemens in 2013, and it was a survey of sling use in members of this society. But, as I tried to say, what they did is they excluded anyone's survey that said they

didn't use slings. And then they concluded that 99 percent of AUGS members use slings, where they should have concluded that 99 percent of AUGS members who use slings use slings. Because they did not count the ones that told them, I don't use slings, and they didn't ask, why don't you use slings? Well, I stopped using them because I found that there were problems with safety associated with the slings.

The second part of their conclusion is only 55 percent of people actually sent the survey back. And in their conclusions they say, these opinions might not represent the opinions of AUGS members at large. So they -- they qualified that this was a study with a low response rate, and they described in their methods that they didn't ask people why they didn't use slings, and they didn't count them if they said they didn't use a sling.

Q. Some of the things that you mentioned, you were asked if you knew the differences between the slings that you used and the Boston Scientific slings. You mentioned they've got different pores. Do you remember that?

A. That is correct.

Q. Different polypropylenes that they're made of, correct?

A. That is correct.

Q. Different additives, right?

A. That is correct.

Q. The edges are different, right?

A. That is correct.
Q. So when companies come to somebody like you and they market their products, do they come in and do they say, "Hey, you ought to use my product, it's just like theirs, except I've only studied it in 36 rabbits?" Do they say that?
A. No.
MR. ADAMS: Objection, Your Honor. This is leading and, again, counsel's testifying, not the expert.
THE COURT: The objection is overruled, Mr. Adams.
BY MR. MONSOUR:
Q. You can answer the question.
A. The answer is "no."
Q. Do they tell you that their products are different or maybe better than their competitors?
A. Yes.
Q. So if a company were to come into this courtroom and say we're just the same as everybody else's, is that what they're telling you doctors on the street?
MR. ADAMS: Objection, argumentative. Also, that's not a proper question for an expert. It has nothing to do with the case.
THE COURT: Do you want to respond to it, counsel, before I rule?
MR. MONSOUR: He opened the door by asking him to compare the slings, Your Honor.

THE COURT: All right. I don't think that answers that it is improper in its form. I'm going to sustain the objection. If you want to rephrase to get into that area, go ahead.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. When they come to sell their products, do they stress that their products are unique?

A. Yes.

Q. Is there ever a time when you were approached by sales reps from any of these companies where they tell you, "We just want you to know our product is exactly like theirs"?

A. No.

Q. Now, one of the questions, one of the things that was brought up is how many of the treating physicians think they've got a good success rate with their products. Do you remember those questions that you got?

A. Yes.

Q. And you were, in fact, asked questions about doctors whose depositions you didn't even review. Do you remember that?

A. Yes.

Q. Okay. And we'll assume that Mr. Adams' numbers were accurate.

But is there any published literature out there that

addresses the concept that physicians think that -- that their interpretations of their own results might be misleading? Are there any articles that are published on that subject?

A. Yes.

Q. Give me the name of this other article.

A. Well, there was a study that came out this year by a Dr. Abbott who -- and her colleagues -- were looking at significant complications that got referred to their institution to manage. And they found that the average patient had two interventions and over 70 percent -- or close to 70 percent needed more than one surgery to fix their complications. What they found is only 26 percent of patients that came to these tertiary centers to get their sling and mesh complications fixed were actually seen at another institution, meaning that there is a very small chance that the doctor that actually put the mesh in knew that this patient even had a complication. And that was one of their conclusions of this study, is that doctors probably don't know that they're getting these complications, and, therefore, they don't know what the level of complication is, and they will be going around thinking that they're doing surgeries that have very few complications because their patients are going to other doctors to take care of those complications.

Q. So let's look at Jeanie Blankenship. Jeanie Blankenship had this product implanted by Dr. Lassere. Her current

physician is Dr. Capelle. Is that correct?
A. That is correct.
Q. Does that happen frequently in this arena?
A. That is correct.
Q. So, if that's the case, when these physicians tell you, "Oh, I've only seen one complaint," does that mean that they're always following up with all of their patients?
A. No. And that's what the Abbott study showed, is that they are not going back to the doctors who implanted the slings in their bodies for their complications.
Q. All right. And I want to address two more things and then I'm going to sit down because I'm sure you all are sick of me. I know the judge is.
(Laughter.)
BY MR. MONSOUR:
Q. I think Mr. Adams thinks I have bushwhacked him with the Cholhan and Ross studies and so I want to pull them back up if we can first. I want to pull up the Ross study first. And --
MR. ADAMS: And, Your Honor, just an objection to whatever I think.
THE COURT: I'm sorry. That objection is sustained, Mr. Monsour.
MR. MONSOUR: And if we could pull up the Ross study and go to the -- go to the first page of it.
(The document was published to the jury.)

BY MR. MONSOUR:
Q. And let's look at this study. It's a randomized controlled trial, right?
A. That is correct.
Q. It -- if you look down below, it talks about who supported the study, correct?
A. That is correct.
Q. And I don't want to -- I don't want anyone to think I'm sneaking up on them. If I look down below, it's a study that received funding from Boston Scientific, right?
MR. ADAMS: Objection, Your Honor. This is cumulative. I mean --
MR. MONSOUR: I'm just trying to clarify a point that he brought up on --
THE COURT: I want to hear the question, Mr. Adams. If there is still an objection, you let me know.
MR. ADAMS: I would.
BY MR. MONSOUR:
Q. This is a Boston Scientific -- funding was received from Boston Scientific, correct?
A. That is correct.
Q. And if we look, it was published in what journal?
A. *Obstetrics and Gynecology*, that we have been calling "The Gray Journal."
Q. "The Gray Journal." And it's not published in an obscure

publication, is it?
A. That is correct.
Q. And when we look at this Boston-Scientific-funded study that was published in a reputable and non-obscure journal, that is Level 1 evidence, when we look at the conclusion -- when we look at the conclusion, the last two sentences of the paper, if we could pull those up, or the last three sentences. I'm sorry.
MR. MONSOUR: That's the wrong one. Ross, last page.
BY MR. MONSOUR:
Q. It says, compared with the TVT group, the transobturator group -- not this group, but the transobturator group -- had tape that was palpable and groin pain. The presence of palpable tape is concerning. Longer follow-up is needed to determine --
MR. ADAMS: (Stands.)
THE COURT: Your objection?
MR. ADAMS: It's cumulative.
THE COURT: That objection is sustained.
MR. MONSOUR: Okay. Let me rephrase my question.
BY MR. MONSOUR:
Q. Did this Boston-Scientific-funded study published in a reputable journal, Level 1 evidence, randomized controlled trial, say don't use the Obtryx?
A. It said that --

MR. ADAMS: This is, again, is cumulative as to what he's covered on direct already.

THE COURT: Do you have a response? Because I tend to agree. My recollection is that it was covered.

MR. MONSOUR: Okay.

THE COURT: No response? I sustain the objection.

MR. MONSOUR: Okay.

BY MR. MONSOUR:

Q. Let me ask this, if we can pull up one last study. And pull up the Cholhan study, if you would.

(The document was published to the jury.)

BY MR. MONSOUR:

Q. And if you can look down in the bottom.

The Cholhan study, just to orient, the Cholhan study, if you pull up the conclusion, is the Obtryx study that talks about palpable tape and how physicians should be aware of periurethral banding, correct?

A. That is correct.

Q. If we go down to the bottom of that page on the left-hand corner, if we look at it, and you pull up about Dr. Cholhan, it does note that he is a consultant and instructor for Boston Scientific; true?

MR. ADAMS: Objection, Your Honor. Again, this is cumulative. This was covered on direct examination.

THE COURT: Response, Mr. Monsour?

MR. MONSOUR: My response is I pulled this up for the jury in my direct and I noted that he was a consultant. And he made the argument that I tried to say that they paid for it, and I'm trying to set the record straight because he misrepresented my question.

THE COURT: Go ahead, please. I'm going to overrule the objection.

BY MR. MONSOUR:

Q. Okay. So all I'm trying to do is establish that I'm proving to the jury what I say is borne out in the documents. Dr. Cholhan is a paid consultant and instructor for Boston Scientific; is that right?

A. That is correct.

Q. And this was not a favorable study?

A. That is correct.

Q. Now, let's talk about the Cholhan study a little bit more. You were asked about the 24 percent dyspareunia rate. Do you remember that?

A. Yes, sir.

Q. In your clinical experience, can you think of a time when you would talk to your patients for treatment of stress urinary incontinence, when you would meet with a woman and say, "Listen, I can do this procedure for you but you've got a one-in-four chance of developing long-term pain with intercourse"? Can you think of any woman that would say yes

to that procedure?

A. No.

MR. MONSOUR: I'll pass the witness.

THE COURT: You can step down, Doctor. Thank you.

(The witness left the stand.)

THE COURT: Call your next witness.

MR. LOVE: Your Honor, at this time the plaintiffs would call Alex Robbins, the training manager and territory manager for Boston Scientific. The plaintiffs' proffer is 17 minutes and 31 seconds.

MR. STRONGMAN: Your Honor, may we approach just briefly on that?

THE COURT: Yes, sir.

MR. STRONGMAN: Your Honor, we've made some objections to the exhibits that are discussed in the Robbins deposition, some of the e-mails that they asked Mr. Robbins about. In addition, a significant portion of the deposition that's going to be played is a discussion of the Cholhan study. I cannot imagine that the jury wants to listen to somebody else walk through the Cholhan study again today at this point.

MR. LOVE: This is a 17 -- this is a 17-minute, does include a brief description of Cholhan, does cover different parts of the study that haven't been covered yet. If you read the e-mail of Dr. Cholhan, who is a paid consultant for Boston

Scientific, sent this study to a Kathleen Fantoni, who is the worldwide global training manager for the company. She did say, she sends it to this gentlemaan, Alex Robbins, who trains key opinion leaders for the company and trains salespeople nationally. And she says, I want your advice on how to use this study. He says three things. He says this study will not help us sell slings, it will not help us defend the company -- he says four things -- it is a negative study, and I would never give it to physicians, and he didn't. It goes straight to claims, our negligence claim, our punitive damage claim, and it refutes essentially much of the cross-examination Rob Adams just did on this expert, that the Cholhan study was A-OK and showed a 79 percent success rate.

THE COURT: You are objecting to the e-mail as an exhibit, counsel?

MR. STRONGMAN: Yeah, well, obviously, the questions regarding the e-mails as well. And Alex Robbins was a sales rep. He didn't train. He was a sales rep. Didn't e-mail anybody in West Virginia, certainly not the doctors in this case. It's -- it's prejudicial, and, again, discussion of the Cholhan study is cumulative, along with everything else.

THE COURT: All right. I certainly do not want to permit cumulative evidence; however, if it addresses different portions of that study, I think it's permissible. And, based on what you all have told me about the e-mail, I find that

e-mail to be relevant with respect to the issues of the plaintiffs' negligence claim and relevant with respect to the punitive damages claims. So I will overrule your objection, Mr. Strongman. And I preserve the defendant's objection and exception to my ruling.

MR. STRONGMAN: Our proffer on the witness is about 15 minutes long.

THE COURT: We will get both of them in today.

(Sidebar concluded.)

(The video testimony of ALEX ROBBINS was played from 4:45 p.m. until 5:03)

THE COURT: Mr. Strongman?

MR. STRONGMAN: Boston Scientific has about a 14-minute proffer for Mr. Robbins.

THE COURT: Mr. Monsour, was there something further?

MR. MONSOUR: No. I was going to offer that was the end of our proffer.

THE COURT: Mr. Love, when you and Mr. Strongman were here at the bench, you did not refer to the exhibit number of that e-mail that I admitted into evidence. Would you place its number on the record for me, please.

MR. LOVE: I will, Your Honor. The e-mail is Exhibit Number 739, and we would move for its admission into evidence.

THE COURT: It is admitted, preserving an objection and exception for the defendant, consistent with the

conversation we had here at the bench.

(PLAINTIFFS' EXHIBIT 739 WAS RECEIVED IN EVIDENCE.)

(The video testimony of ALEX ROBBINS continued at 5:04 p.m.)

MR. STRONGMAN: That concludes our proffer of Mr. Robbins.

THE COURT: All right. Thank you.

Ladies and gentlemen, I'm going to release you for the evening. While you're out, do not discuss the case among yourselves or permit anyone to discuss it with you or in your presence, and remember that you are under continuing order not to read, listen to, or view any media coverage that there might be of the trial. Have a good, restful evening, and we will begin tomorrow morning at 9. We'll stand in recess for your purposes.

(The Jury left the courtroom at 5:17 p.m.)

THE COURT: Are there other matters, counsel, that we need to address here this afternoon?

MR. LOVE: I've got some exhibits from depos we played the first day. I can do it first thing tomorrow, I can do it now.

THE COURT: Let's do it.

MS. WEILER: We also have the medical records of Ms. Wilson available. We can do those now, Your Honor, as well.

THE COURT: Thank you, Ms. Weiler.

MR. LOVE: The first thing is the key points memo, I don't think it's been officially offered, but it's Exhibit 759. The plaintiffs would offer it pursuant to the objections made by the defendants.

MR. STRONGMAN: I think it's in evidence.

THE COURT: You believe that it has previously been admitted, Mr. Strongman?

MR. STRONGMAN: I do. Mr. Monsour admitted the first page --

THE COURT: The clerk indicates that it has been admitted.

MR. STRONGMAN: Okay. Thank you, Your Honor.

MR. MONSOUR: I don't believe I -- I think I forgot to offer it in its entirety. I think the first page is in but I think we might need the other pages with it, Your Honor, just for clarification.

MR. LOVE: I will make sure the clerk has a copy.

THE COURT: Thank you.

MR. LOVE: The next is from the deposition of Rob Miragliuolo, and these are Exhibits 639, 525, and that's it for Rob Miragliuolo.

THE COURT: Any objection?

MR. STRONGMAN: No objection on those documents.

THE COURT: All right. Plaintiffs' Exhibits 639 and

525 will be admitted into evidence without objection.
(PLAINTIFFS' EXHIBITS 639 and 525 WERE RECEIVED IN EVIDENCE.)
MR. STRONGMAN: And, actually, just say subject to the issues we have already raised and that have been disposed of in motions in limine.
THE COURT: All right.
MR. LOVE: Next is from the deposition of Charles Smith and it's Exhibit 863, Exhibit 864 -- I'm sorry. Let me back up. I was reading the wrong exhibit number. Let me start over.
This is the Charles Smith deposition. It is Plaintiffs' Exhibit 1115, Plaintiffs' Exhibit 1061, and Plaintiffs' Exhibit 966.
THE COURT: Mr. Strongman?
MR. STRONGMAN: Same with respect to those, just with respect -- no objection other than those that have been already been raised, the motions in limine and that have been denied by the Court.
THE COURT: All right. Plaintiffs' Exhibits 1115, 1061, and 966 will be admitted into evidence subject to the prior rulings of the Court.
(PLAINTIFFS' EXHIBITS 1115, 1061, and 966 WERE RECEIVED IN EVIDENCE.)
MR. LOVE: The final deposition is Evan Brasington, and it is Plaintiffs' Exhibit 553, Plaintiffs' Exhibit 981,

Plaintiffs' Exhibit 517, Plaintiffs' Exhibit 564, and Plaintiffs' Exhibit 532.

MR. STRONGMAN: Again, this is just subject to the ProteGen objections that were argued on this deposition.

THE COURT: All right. Plaintiffs' Exhibits 517, 532, 553, 564, and 981 will be admitted into evidence, preserving to the defendant the objections that have previously been made.

(PLAINTIFFS' EXHIBITS 517, 532, 553, 564, and 981 WERE RECEIVED IN EVIDENCE.)

MR. STRONGMAN: Thank you, Your Honor.

THE COURT: Ms. Weiler?

MS. WEILER: Thank you.

We would like to move into evidence joint medical exhibits of Ms. Wilson. First is Exhibit Number 91, medical records from Subhash Bhanot, M.D.; Number 92, medical records regarding Ms. Wilson from CAMC Health Systems, Incorporated; Exhibit Number 93, medical records of Ms. Wilson from Dr. Lana D. Christiana; medical records of Ms. Wilson as Exhibit 94 from CVS Corporation; Exhibit Number 95, the medical records of Ms. Wilson from Dr. Thopsie V. Jagannath. I will provide the Court with some spellings in a moment. Exhibit Number 96, medical records from Ms. Wilson from Logan Regional Medical Center; Exhibit Number 97, medical records of Ms. Wilson from Dr. Cyrus Mali; Exhibit Number 98, the medical records of

Ms. Wilson from Montgomery General Hospital; Exhibit Number 99, medical records of Ms. Wilson from Prestera Center; Exhibit Number 100, medical records of Ms. Wilson from Rite Aid Corporation; Exhibit Number 101, medical records of Ms. Wilson from Saint Francis Hospital; Exhibit Number 102, medical records of Ms. Wilson from Ujjal S. Sandhu, M.D.; and Exhibit Number 103, the medical records of Ms. Wilson from WVU Healthcare.

THE COURT: Anything that the plaintiff wants to place on the record regarding these joint exhibits?

MR. LOVE: We have no objection, Your Honor.

THE COURT: Joint Exhibits 91 through and including 103 with respect to Plaintiff Wilson will be admitted into evidence.

MS. WEILER: Thank you, Your Honor.

(JOINT EXHIBITS 91 THROUGH 103 WERE RECEIVED IN EVIDENCE.)

THE COURT: Any other matters this evening?

MR. LOVE: Not on our end, Your Honor.

MR. ADAMS: Nor ours.

THE COURT: Have a good evening.

MR. ADAMS: Thank you, Your Honor.

COURT SERVICES OFFICER: All rise.

(The proceedings concluded at 5:24 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, RSA, Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Lisa A. Cook, RPR, RMR, CRR, FCRR,** do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR **11/04/14**
Court Reporter **Date**

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR **11/04/14**
Court Reporter **Date**

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